## **EPA Jacket 85806-4**

### **DATA PACKAGE BEAN SHEET**

Date: 07-Oct-2015
Page 1 of 2

Decision #: 507395

DP #: (429490)

PRIA

Parent DP #:

**Submission #: 971922** 

E-Sub #:

## \* \* \* Registration Information \* \* \*

Registration:	85806-4 - AGSA	/ER DICAMBA	TECHNI	CAL				
Company:	85806 - AGSAVER II	LLC						
Risk Manager:	RM 23 - Kathryn Mon	tague - (703) 305-1	243 Room	# PY1 S-73	32	<u>.                                    </u>		
Risk Manager Reviewer:	Karen Samek KSAM	EK				·		
Sent Date:		PR	IA Due Da	te: <u>19-Apr</u> -	2016	2. 1	Edited Due Date:	
Type of Registration:	Product Registration	- Section 3				•		
Action Desc:	(R351) AMENDMEN	;UNREGISTERED	SOURCE	OF ACTIVE	INGRE	DIENT;		
Ingredients:	029801, Dicamba(98	.9%)				•		
		10-10				•		
	*	* * Data Pacl	kage Ir	format	ion *	* *		
Expedite:	◯ Yes ● No		Date Se	ent: <u>07-Oct</u> -	-2015	_	Due Back:	
DP Ingredient:	029801, Dicamba							
DP Title:	Product Chemistry R	eview for Reg. No. 8	35806-4					
CSF Included:	O Yes ● No	Label Included:	O Yes	● No	Parer	nt DP #:		
Assigned To	<u>o</u> _	Date	in	Date	Out			
Organization: RD / C	CITAB					Last Possible	Science Due Date:	19-Feb-2016
Team Name:							Science Due Date:	
Reviewer Name:						Sub Data	Package Due Date:	
Contractor Name:	<del></del>							

#### \* \* \* Studies Sent for Review \* \* \*

Printed on Page 2

## \* \* \* Additional Data Package for this Decision \* \* \*

No Additional Data Packages

## \* \* \* Data Package Instructions \* \* \*

Please provide a 90-day Technical Screen by 11/13/15.

Please review the product chemistry data for this request to add an unregistered source of the active ingredient for Reg. No. 85806-4 and provide a DER/CSF review. The product chemistry data includes MRIDs 49683601, 49683602, 49683603, and 49683604. Attached are copies of the cover letter/transmittal information, label, CSF, and product chemistry data to be reviewed. If you have any questions please contact Karen Samek at 703-347-8825. Thanks.

\* \* \* Studies Sent for Review \* \* \*

Decision#: (507395)

DP#: (429490)		* * * Studies Sent for Review *	* *	Decision#: (507395)
MRID	MRID Status	Citation Reference	Guideline	86-5 Status
49683601		Butz, R. (2015) AgSaver(TM) Dicamba Technical: Product Identity and Composition, Description of Beginning Materials and Manufacturing Process, Discussion of Formation of Impurities, Certified Limits, Analytical Method. Project Number: 201501, W0276761/3. Unpublished study prepared by AgSaver II, LLC. 71p.	830.1550/Product Identity and composition	
49683601		Butz, R. (2015) AgSaver(TM) Dicamba Technical: Product Identity and Composition, Description of Beginning Materials and Manufacturing Process, Discussion of Formation of Impurities, Certified Limits, Analytical Method. Project Number: 201501, W0276761/3. Unpublished study prepared by AgSaver II, LLC. 71p.	830.1600/Description of materials used to produce the product	Pass (17-Aug-2015)
49683601		Butz, R. (2015) AgSaver(TM) Dicamba Technical: Product Identity and Composition, Description of Beginning Materials and Manufacturing Process, Discussion of Formation of Impurities, Certified Limits, Analytical Method. Project Number: 201501, W0276761/3. Unpublished study prepared by AgSaver II, LLC. 71p.	830.1620/Description of production process	Pass (17-Aug-2015)
49683601		Butz, R. (2015) AgSaver(TM) Dicamba Technical: Product Identity and Composition, Description of Beginning Materials and Manufacturing Process, Discussion of Formation of Impurities, Certified Limits, Analytical Method. Project Number: 201501, W0276761/3. Unpublished study prepared by AgSaver II, LLC. 71p.	830.1670/Discussion of formation of impurities	Pass (17-Aug-2015)
49683601		Butz, R. (2015) AgSaver(TM) Dicamba Technical: Product Identity and Composition, Description of Beginning Materials and Manufacturing Process, Discussion of Formation of Impurities, Certified Limits, Analytical Method. Project Number: 201501, W0276761/3. Unpublished study prepared by AgSaver II, LLC. 71p.	830.1750/Certified limits	Pass (17-Aug-2015)
49683601		Butz, R. (2015) AgSaver(TM) Dicamba Technical: Product Identity and Composition, Description of Beginning Materials and Manufacturing Process, Discussion of Formation of Impurities, Certified Limits, Analytical Method. Project Number: 201501, W0276761/3. Unpublished study prepared by AgSaver II, LLC. 71p.	830.1800/Enforcement analytical method	Pass (17-Aug-2015)
49683602		Sun, G. (2009) Preliminary Analysis of Dicamba Technical Grade Active Ingredient: Final Report. Project Number: 01/14863/02/001, GLP/SP/064. Unpublished study prepared by Southwest Research Institute. 40p.	830.1700/Preliminary analysis	Pass (17-Aug-2015)
49683602		Sun, G. (2009) Preliminary Analysis of Dicamba Technical Grade Active Ingredient: Final Report. Project Number: 01/14863/02/001, GLP/SP/064. Unpublished study prepared by Southwest Research Institute. 40p.	830.1800/Enforcement analytical method	Pass (17-Aug-2015)
49683603		Sun, G. (2015) Polychlorinated Dibenzodioxins and Polychlorinated Dibenzofurans Analysis of Dicamba TGAI: Final Report. Project Number: 01/14863/02/003, GLP/SP/066, 090521/1. Unpublished study prepared by Southwest Research Institute. 99p.		Pass (17-Aug-2015)
49683603		Sun, G. (2015) Polychlorinated Dibenzodioxins and Polychlorinated Dibenzofurans Analysis of Dicamba TGAI: Final Report. Project Number: 01/14863/02/003, GLP/SP/066, 090521/1. Unpublished study prepared by Southwest Research Institute. 99p.	analytical method	Pass (17-Aug-2015)

\* \* \* Studies Sent for Review \* \* \*

Decision#: (507395)

DP#: (429490)		* * * Studies Sent for Review *	**	Decision#: (507395)
MRID	MRID Status	Citation Reference	Guideline	86-5 Status
19683604		Miller, R. (2013) Physical and Chemical Characteristics of Dicamba 98%: Final Report. Project Number: ARC/EX/1365, ARC/EX/1365/017/P/1, ARC/EX/1365/001/P. Unpublished study prepared by Analytical & Regulatory Chemistry, Inc. 72p.	830.6302/Color	Pass (17-Aug-2015)
19683604		Miller, R. (2013) Physical and Chemical Characteristics of Dicamba 98%: Final Report. Project Number: ARC/EX/1365, ARC/EX/1365/017/P/1, ARC/EX/1365/001/P. Unpublished study prepared by Analytical & Regulatory Chemistry, Inc. 72p.	830.6303/Physical state	Pass (17-Aug-2015)
9683604		Miller, R. (2013) Physical and Chemical Characteristics of Dicamba 98%: Final Report. Project Number: ARC/EX/1365, ARC/EX/1365/017/P/1, ARC/EX/1365/001/P. Unpublished study prepared by Analytical & Regulatory Chemistry, Inc. 72p.	830.6304/Odor	Pass (17-Aug-2015)
\$9683604		Miller, R. (2013) Physical and Chemical Characteristics of Dicamba 98%: Final Report. Project Number: ARC/EX/1365, ARC/EX/1365/017/P/1, ARC/EX/1365/001/P. Unpublished study prepared by Analytical & Regulatory Chemistry, Inc. 72p.	830.6313/Stability to normal and elevated temperatures, metals, and metal ions	Pass (17-Aug-2015)
19683604		Miller, R. (2013) Physical and Chemical Characteristics of Dicamba 98%: Final Report. Project Number: ARC/EX/1365, ARC/EX/1365/017/P/1, ARC/EX/1365/001/P. Unpublished study prepared by Analytical & Regulatory Chemistry, Inc. 72p.	830.6314/Oxidizing or reducing action	Pass (17-Aug-2015)
49683604	·	Miller, R. (2013) Physical and Chemical Characteristics of Dicamba 98%: Final Report. Project Number: ARC/EX/1365, ARC/EX/1365/017/P/1, ARC/EX/1365/001/P. Unpublished study prepared by Analytical & Regulatory Chemistry, Inc. 72p.	830.6317/Storage stability	Pass (17-Aug-2015)
49683604		Miller, R. (2013) Physical and Chemical Characteristics of Dicamba 98%: Final Report. Project Number: ARC/EX/1365, ARC/EX/1365/017/P/1, ARC/EX/1365/001/P. Unpublished study prepared by Analytical & Regulatory Chemistry, Inc. 72p.	830.6320/Corrosion characteristics	Pass (17-Aug-2015)
19683604		Miller, R. (2013) Physical and Chemical Characteristics of Dicamba 98%: Final Report. Project Number: ARC/EX/1365, ARC/EX/1365/017/P/1, ARC/EX/1365/001/P. Unpublished study prepared by Analytical & Regulatory Chemistry, Inc. 72p.	830.7000/pH	Pass (17-Aug-2015)
49683604		Miller, R. (2013) Physical and Chemical Characteristics of Dicamba 98%: Final Report. Project Number: ARC/EX/1365, ARC/EX/1365/017/P/1, ARC/EX/1365/001/P. Unpublished study prepared by Analytical & Regulatory Chemistry, Inc. 72p.	830.7050/UV/Visible absorption	Pass (17-Aug-2015)
19683604		Miller, R. (2013) Physical and Chemical Characteristics of Dicamba 98%: Final Report. Project Number: ARC/EX/1365, ARC/EX/1365/017/P/1, ARC/EX/1365/001/P. Unpublished study prepared by Analytical & Regulatory Chemistry, Inc. 72p.	830.7200/Melting point/melting range	Pass (17-Aug-2015)
49683604		Miller, R. (2013) Physical and Chemical Characteristics of Dicamba 98%: Final Report. Project Number: ARC/EX/1365, ARC/EX/1365/017/P/1, ARC/EX/1365/001/P. Unpublished study prepared by Analytical & Regulatory Chemistry, Inc. 72p.	830.7300/Density/relative density	Pass (17-Aug-2015)



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DATA MATRIX				
Date: July 28, 2015	EPA Reg No./ File Symbol 85806-4	Page 1 of 14		
Applicant's/Registrant's Name and Address:  AgSaver II, LLC	Product:			
203 E. Ash Ave. McGehee, AR 71654	AgSaver Dicamba Technical			
Ingredient: Dicamba	·			

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Product Properties				
830.1550	Product Identity and Composition	Volume 2 49273301	AgSaver II, LLC AgSaver II, LLC	OWN	
830.1600	Description of materials used to produce the product	Volume 2 49273301	AgSaver II, LLC AgSaver II, LLC	OWN OWN	
830.1620	Description of production process	Volume 2 49273301	AgSaver II, LLC AgSaver II, LLC	OWN OWN	
830.1670	Formation of Impurities	Volume 2 49273301	AgSaver II, LLC AgSaver II, LLC	OWN OWN	
830.1700	Preliminary Analysis	Volume 2 49273302 49565101	AgSaver II, LLC AgSaver II, LLC AgSaver II, LLC	OWN OWN OWN	
830.1750	Certification of Limits	Volume 2 49273301	AgSaver II, LLC AgSaver II, LLC	OWN OWN	
830.1800	Analytical Method	Volume 2 Volume 3 Volume 4 49273302	AgSaver II, LLC AgSaver II, LLC AgSaver II, LLC AgSaver II, LLC	OWN OWN OWN	

Signature Signature	Name and Title	Date
11111	Robert G. Butz,	7/28/2015
Mant S, Suit	Authorized Agent for AgSaver II, LLC	
	Sullivan & Worcester LLP	

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DATA MATRIX				
Date: July 28, 2015	EPA Reg No./ File Symbol 85806-4	Page 2 of 14		
Applicant's/Registrant's Name and Address: AgSaver II, LLC	Product:	,		
203 E. Ash Ave.	AgSaver Dicamba Technical			
McGehee, AR 71654				
Ingredient: Dicamba				

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
-		49565101	AgSaver II, LLC	OWN	
830.6302	Color	49273303	AgSaver II, LLC	OWN	
830.6303	Physical State	49273303	AgSaver II, LLC	OWN	
830.6304	Odor	49273303	AgSaver II, LLC	OWN	
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	49273303	AgSaver II, LLC	OWN	
830.6314	Oxidation/reduction: Chemical Incompatibility	49273303	AgSaver II, LLC	OWN	
830.6315	Flammability	N/A	AgSaver II, LLC	N/A	N/A per 830.1000
830.6316	Explodability	N/A	AgSaver II, LLC	N/A	N/A per 830.1000
830.6320	Corrosion Characteristics	49273303	AgSaver II, LLC	OWN	
830.6376	Storage Stability	49273303	AgSaver II, LLC	OWN	
830.7000	pH	49273303	AgSaver II, LLC	OWN	1
830.7050	UV/Visible Absorption	49273303	AgSaver II, LLC AgSaver II, LLC	OWN	
Signature			Name and Title		Date

Signatu. c Let S. Buy

{W0277281; 1}

Name and Title Robert G. Butz, Authorized Agent for AgSaver II, LLC Sullivan & Worcester LLP

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	DATA MATRIX	
Date: July 28, 2015	EPA Reg No./ File Symbol 85806-4	Page 3 of 14
Applicant's/Registrant's Name and Address:	Product:	
AgSaver II, LLC		
203 E. Ash Ave.	AgSaver Dicamba Technical	
McGehee, AR 71654		
Ingredient: Dicamba		<del></del>

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7200	Melting Point	49273303	AgSaver II, LLC	OWN	
830.7300	Density	49273303	AgSaver II, LLC	OWN	
830.7370	Dissociation Constants in Water	43288001, 43140308, 44520902	SANDOZ AGRO INC SANDOZ AGRO INC ALBAUGH INC	OLD OLD OLD	
830.7550	Partition coefficient, shake flask method	41966601 23106	SANDOZ AGRO INC VELSICOL CHEMICAL CORP	OLD OLD	
830.7570	Octanol/Water Partition	44520902	ALBAUGH INC	OLD	
830.7840	Solubility	23106, 44520902	VELSICOL CHEMICAL CORP ALBAUGH INC	OLD OLD	
830.7950	Vapor Pressure	23106	VELSICOL CHEMICAL CORP	OLD	
	Fate, Transport and Transformation				
835.1240	Leaching/Adsorption/Desorption	42774101, 43095301	Sandoz Agro, Inc. Sandoz Agro, Inc.	OLD OLD	
835.1410	Laboratory Volatilization	41966602	Sandoz Crop Prot. Corp.	OLD	

Signature	Name and Title	Date
Relat S. But	Robert G. Butz, Authorized Agent for AgSaver II, LLC	7/28/2015
ί	Sullivan & Worcester LLP	

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DATA MATRIX				
Date: July 28, 2015	EPA Reg No./ File Symbol 85806-4	Page 4 of 14		
Applicant's/Registrant's Name and Address:  AgSaver II, LLC	Product:			
203 E. Ash Ave. McGehee, AR 71654	AgSaver Dicamba Technical			
Ingredient: Dicamba				

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
835.2120	Hydrolysis	40335501	Velsicol Chemical Corporation,	OLD	
835.2240	Photodegradation - Water	42774103	Sandoz Agro, Inc	OLD	· · · · · · · · · · · · · · · · · · ·
835.2410	Photodegradation - Soil	42774103	Sandoz Agro, Inc	OLD	
835.4100	Aerobic Soil Metabolism	43245207	Sandoz Agro. Inc	OLD	
835.4200	Anaerobic Soil Metabolism	43245208	Sandoz Agro. Inc	OLD	
835.4300	Aerobic Aquatic Metabolism	43758509	Sandoz Agro. Inc	OLD	
835.4400	Anaerobic Aquatic Metabolism	43245208	Sandoz Agro. Inc	OLD	•
835.6100	Terrestrial Field Dissipation	42754101, 42754102, 44361526	Sandoz Agro, Inc. Sandoz Agro, Inc. UNKNOWN	OLD OLD OLD	
835.8100	Fate in Soil - Leaching & Adsorption/Desorption	48876002 47434312	MONSANTO U.S. EPA	PL PL	
	Spray Drift				
840.1100	Spray Droplet Size Spectrum	Cite-all	Spray Drift Task Force	PAY	

Signature	Name and Title	Date
11/407/	Robert G. Butz,	7/28/2015
Holand S, South	Authorized Agent for AgSaver II, LLC	
	Sullivan & Worcester LLP	

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	DATA MATRIX	
Date: July 28, 2015	EPA Reg No./ File Symbol 85806-4	Page 5 of 14
Applicant's/Registrant's Name and Address:  AgSaver II, LLC  203 E. Ash Ave.	Product:  AgSaver Dicamba Technical	
McGehee, AR 71654		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
840.1200	Spray Drift Field Deposition	Cite-all	Spray Drift Task Force	PAY	
	Ecological Effects				
850.1010	Freshwater Invertebrate Toxicity	00052126	VELSICOL CHEMICAL CORP	OLD	
850.1010	Invertebrate Toxicity - TEP	40094602	U.S. FISH & WILDLIFE	PL	
850.1025	Estuarine/Marine Toxicity - Mollusk	40228401	U.S. EPA	OLD	
850.1035	Estuarine/Marine Toxicity - Shrimp	00034702	VELSICOL CHEMICAL CORP	OLD	
850.1075	Fish Toxicity Bluegill	00034703	VELSICOL CHEMICAL CORP	OLD	
850.1075	Fish Toxicity Bluegill — TEP	40098001	US Fish & Wildlife Service	PL	
850.1075	Freshwater Fish Toxicity Rainbow Trout	00041272	VELSICOL CHEMICAL CORP	OLD	
850.1075	Freshwater Fish Toxicity Rainbow Trout - TEP	00036915	VELSICOL CHEMICAL CORP	OLD	
850.1075	Estuarine/Marine Toxicity - Fish	00025390 45205107	VELSICOL CHEMICAL CORP U.S. EPA	OLD PL	· · · · · · · · · · · · · · · · · · ·
850.2100	Avian Acute Oral Toxicity-Duck	42774106	SANDOZ AGRO INC	OLD OLD	

Signature	Name and Title	Date
111676	Robert G. Butz,	7/28/2015
Mart S. Sut	Authorized Agent for AgSaver II, LLC	
1	Sullivan & Worcester LLP	

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## Date: July 28, 2015 Applicant's/Registrant's Name and Address: AgSaver II, LLC 203 E. Ash Ave. DATA MATRIX EPA Reg No./ File Symbol 85806-4 Product: Product: AgSaver Dicamba Technical

McGehee, AR 71654 Ingredient: Dicamba

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.2100	Avian Acute Oral Toxicity-Quail	42774105	SANDOZ AGRO INC	OLD	
850.2300	Avian Reproduction - Quail	43814004	SANDOZ AGRO INC	OLD	
850.2300	Avian Reproduction — Duck	43814003	SANDOZ AGRO INC	OLD	
850.3020	Honey Bee Acute Contact	00036935	ENIMONT AMERICA, INC	OLD	
850.4100	Seedling Germination and Seedling Emergence, Tier I	42846301	SANDOZ AGRO INC	OLD	-
850.4150	Vegetative Vigor, Tier I	42846301	SANDOZ AGRO INC	OLD	
850.4200	Effects on Non-Target Plants - Seed Germination & Vegetative Vigor	48718014	BASF CORPORATION	PAY	
850.4225	Seedling Germination and Seedling Emergence, Tier II	48001301	BASE CORPORATION	PAY .	
850.4250	Vegetative Vigor, Tier II	48001302	BASF CORPORATION	PAY	
850.4400	Aquatic Plant Toxicity testing using Lemna, sp.	45088212	U.S. EPA	PL.	····
850.5400	Aquatic Plant Growth	42774107, 42774108,	SANDOZ AGRO INC SANDOZ AGRO INC	OLD OLD	

Signature	Name and Title	Date
Relat S. But	Robert G. Butz, Authorized Agent for AgSaver II, LLC	7/28/2015
<i>l</i>	Sullivan & Worcester LLP	

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## Date: July 28, 2015 Applicant's/Registrant's Name and Address: AgSaver II, LLC 203 E. Ash Ave. McGehee, AR 71654 Ingredient: Dicamba EPA Reg No./ File Symbol 85806-4 Product: AgSaver Dicamba Technical

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		42774109,	SANDOZ AGRO INC	OLD	
		42774100,	SANDOZ AGRO INC	OLD	
		42774110	SANDOZ AGRO INC	OLD	
	Residue Chemistry				
860.1300	Nature of Residue — Plants	40642801	SANDOZ AGRAO INC	OLD	
860.1300	Nature of Residue — Livestock	43461701	WELLMARK INTERNATIONAL	OLD	
860.1340	Residue Analytical Method — Plants	40233501,	SANDOZ AGRO INC	OLD	
		40547911,	SANDOZ AGRO INC	OLD	
		41187301,	SANDOZ AGRO INC	OLD	
		42675901,	SANDOZ AGRO INC	OLD	
		42883202,	SANDOZ AGRO INC	OLD	
		43245203,	SANDOZ AGRO INC	OLD	
	<u> </u>	43245205,	SANDOZ AGRO INC	OLD	•
	1	43245205,	SANDOZ AGRO INC	OLD	
		43245206,	SANDOZ AGRO INC	OLD	
		43274501,	SANDOZ AGRO INC	OLD	
-		43370701,	WELLMARK INTERNATIONAL	OLD	

Signature
1664 S. But

Name and Title
Robert G. Butz,
Authorized Agent for AgSaver II, LLC
Sullivan & Worcester LLP

Date 7/28/2015

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# Date: July 28, 2015 Applicant's/Registrant's Name and Address: AgSaver II, LLC 203 E. Ash Ave. McGehee, AR 71654 Ingredient: Dicamba EPA Reg No./ File Symbol 85806-4 Page 8 of 14 85806-4 Product: AgSaver Dicamba Technical

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		43425803,	SANDOZ AGRO INC	OLD	
		43866601,	SANDOZ AGRO INC	OLD	
		43814101,	SANDOZ AGRO INC	OLD	ļ
		44089302,	SANDOZ AGRO INC	OLD	
		44089303,	SANDOZ AGRO INC	OLD	
		44089304,	SANDOZ AGRO INC	OLD	
		44089305,	SANDOZ AGRO INC	OLD	
		44891302,	BASE CORPORATION	PAY	
		44891303,	BASF CORPORATION	PAY	
		45196801,	BASE CORPORATION	PAY	
		43814001	SANDOZ AGRO INC	OLD	
•		48001303	BASF CORP	PAY	
860.1340	Residue Analytical Method - Livestock	Data gap		GAP	RED
860.1360	Multiresidue Methods	48001304	BASF CORP	PAY	
860.1380	Storage Stability- sugarcane molasses	Data gap		GAP	RED
860.1380	Storage Stability- animal commodities	Data gap		GAP	RED
860.1480	MCR - Cattle, Goats, Horses and Sheep Meat	00079742	VELSICOL CHEMICAL CORP	OLD	
Signature			Name and Title	<del></del>	Date

Signature

1648, But

Name and Title
Robert G. Butz,
Authorized Agent for AgSaver II, LLC
Sullivan & Worcester LLP

7/28/2015

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## Date: July 28, 2015 Applicant's/Registrant's Name and Address: AgSaver II, LLC 203 E. Ash Ave. McGehee, AR 71654 Ingredient: Dicamba EPA Reg No./ File Symbol 85806-4 Page 9 of 14 85806-4 AgSaver Dicamba Technical

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1480	MOR - Cattle, Goats, Horses and Sheep Meat Byproducts	00079742	VELSICOL CHEMICAL CORP	OLD	
860.1480	MOR - Cattle, Goats, Horses and Sheep Fat	00079742	VELSICOL CHEMICAL CORP	OLD	
860.1480	MOR - Milk	00116671	VELSICOL CHEMICAL COR	OLD	
860.1500	MOR - Corn, Grain	44089303	SANDOZ AGRO INC	OLD	
860.1500	MOR - Corn, Stover	44089303	SANDOZ AGRO INC	OLD	
860.1500	MOR - Corn, Sweet	48001305	BASF CORPORATION	PAY	
860.1500	Corn, Forage	44089303	SANDOZ AGRO INC	OLD	
860.1500	MOR - Soybean, forage	40001901 41387001	SANDOZ AGRO INC SANDOZ AGRO INC	OLD · OLD	
860.1500	MOR - Soybean, hay	40001901 41387001	SANDOZ AGRO INC SANDOZ AGRO INC	OLD OLD	
860.1500	MOR - Sugarcane	00030701 44089302	VELSICOL CHEMICAL CORP SANDOZ AGRO INC	OLD OLD	
860.1500	MOR - Sorghum, Grain	43245203	SANDOZ AGRO INC	OLD	

Signature	Name and Title	Date
111407	Robert G. Butz,	7/28/2015
Mari S, Suit	Authorized Agent for AgSaver II, LLC	
	Sullivan & Worcester LLP	

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# Date: July 28, 2015 Applicant's/Registrant's Name and Address: AgSaver II, LLC 203 E. Ash Ave. McGehee, AR 71654 Ingredient: Dicamba DATA MATRIX EPA Reg No./ File Symbol 85806-4 Page 10 of 14 Page 10 of 14 AgSaver Dicamba Product: AgSaver Dicamba Technical

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1500	MOR -Sorghum, Stover	44089306	SANDOZ AGRO INC	OLD	
860.1500	MOR - Sorghum, Forage	43245203	SANDOZ AGRO INC	OLD	
860.1500	MOR - Stalk, Stem, and Leaf Petiole Vegetables	48499801	INTERREGIONAL RESEARCH PROJECT NO. 4 (IR-4)	PL	
860.1500	MOR - Wheat, Grain	44089305	SANDOZ AGRO INC	OLD	
860.1500	MOR - Wheat, Forage	43274501	SANDOZ AGRO INC	OLD	
860.1500	MOR - Wheat, Straw	44089305	SANDOZ AGRO INC	OLD	
860.1520	Magnitude of Residue in Processed Food/Feed; Wheat	40663801, 42675901	SANDOZ AGRO INC SANDOZ AGRO INC	OLD OLD	
860.1560	Reasonable Grounds in Support of Petition - Exposure or Risk to Non-Target Organisms	48457909	U.S. EPA	PL	
860.1850	Confined Accumulation in Rotational Crops	41972001, 43698601	SANDOZ WELLMARK INTERNATIONAL	OLD OLD	
	Health Effects				
870.1100	Acute Oral Toxicity	00078444	VELSICOL CHEMICAL CORP	OLD	RED

Signature	*	Name and Title	Date
11 40 -	7 /-	Robert G. Butz,	7/28/2015
Holand S,	Suit	Authorized Agent for AgSaver II, LLC	
, =	- <i>l</i>	Sullivan & Worcester LLP	

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WASHINGTON, D.C. 20460

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# Date: July 28, 2015 Applicant's/Registrant's Name and Address: AgSaver II, LLC 203 E. Ash Ave. McGehee, AR 71654 Ingredient: Dicamba EPA Reg No./ File Symbol 85806-4 Product: AgSaver Dicamba Technical

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.1200	Acute Dermal Toxicity	00241584	UNKNOWN	OLD	RED
870.1300	Acute Inhalation Toxicity	00263861	UNKNOWN	OLD	RED
870.2400	Acute Eye Irritation	00241584	UNKNOWN	OLD	RED
870.2500	Acute Dermal Irritation	00237955	UNKNOWN	OLD	RED
870.2600	Dermal Sensitization	00263861	UNKNOWN	OLD	RED
870.3100	Subchronic Oral Toxicity: 90- Day Study Rodent	44623101	BASE CORPORATION	OLD	
870.3150	Subchronic Oral Toxicity: 90- Day Study Non- rodent	44623101	BASF CORPORATION	OLD	
870.3200	21-Day Dermal - Rabbit/Rat	40547901, 45814501	SANDOZ AGRO INC BASF CORPORATION	OLD OLD	
870.3550	Developmental Toxicity - Mice	46074401	U.S. EPA	PL	
870.3700	Developmental Toxicity - Rat	00084024	Velsicol Chemical Corp.	OLD	
870.3700	Developmental Toxicity - Rabbit	42429401	SANDOZ AGRO INC	OLD	<del> </del>
870.3800	2-Generation Reproduction - Rat	43137101	SANDOZ AGRO INC	OLD	<del>                                     </del>

Signature	Name and Title	Date
11/407/	Robert G. Butz,	7/28/2015
Holand S. Suit	Authorized Agent for AgSaver II, LLC	
	Sullivan & Worcester LLP	

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# Date: July 28, 2015 Applicant's/Registrant's Name and Address: AgSaver II, LLC 203 E. Ash Ave. McGehee, AR 71654 Ingredient: Dicamba DATA MATRIX EPA Reg No./ File Symbol 85806-4 Product: AgSaver Dicamba Technical

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.4100	Chronic Feeding Toxicity - Rat	42774104	SANDOZ AGRO INC	OLD	
870.4100	Chronic Feeding Toxicity Study - Rat	00145150	E. I. DUPONT DE NEMOURS	OLD	
870.4100	Chronic Feeding Toxicity Study - Non-rodent	40321102, 43245210	SANDOZ AGRO INC SANDOZ AGRO INC	OLD OLD	· · · · · · · · · · · · · · · · · · ·
870.4200	Carcinogenicity Mice	40872401	SANDOZ AGRO INC	OLD	
870.4300	Combined Chronic Toxicity/Carcinogenicity: Rats	00145150	E. I. DUPONT DE NEMOURS	OLD	
870.5100	Bacterial Reverse Gene Mutation	40321101	SANDOZ AGRO INC	OLD	
870.5375	Cytogenetics	40321101, 00143001	SANDOZ AGRO INC VELSICOL CHEMICAL CORP	OLD OLD	
870.5550	Unscheduled DNA Synthesis in Mammalian Cells in Culture	00143001	VELSICOL CHEMICAL CORP	OLD	
870.7485	General Metabolism	44609801	BASF CORPORATION	OLD	
870.7800	Immunotoxicity	48081601	BASF CORP	PAY	
	Occupational and Residential Exposure				

Signature	Name and Title	Data
Signature	Name and Title	Date
1114074	Robert G. Butz,	7/28/2015
The Sunt	Authorized Agent for AgSaver II, LLC	
	Sullivan & Worcester LLP	

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# Date: July 28, 2015 Applicant's/Registrant's Name and Address: AgSaver II, LLC 203 E. Ash Ave. McGehee, AR 71654 Ingredient: Dicamba EPA Reg No./ File Symbol 85806-4 Page 13 of 14 Page 13 of 14 85806-4 AgSaver Dicamba Technical

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
875.1000	Background for Application Exposure Monitoring	Cite-All	AHETF	PAY	
875.1100	Dermal Exposure -Outdoor	Cite-All	AHETF	PAY	
875.1200	Dermal Exposure - Indoor	Cite-All	ARTF, AHETF	PAY	
875.1300	Inhalation Exposure -Outdoor	Cite-All	ARTF. AHETF	PAY	
875.1400	Inhalation Exposure -Indoor	47464517	U.S. EPA	PL	
875.2100	Foliar Dislodgeable Residue Dissipation	Cite-All	ARTF	PAY	
875.2200	Soil Residue Dissipation	44959001 47299308	SYNGENTA CROP PROTECTION, LLC U.S. EPA	PAY PL	RED <sup>1</sup>
875.2400	Dermal Exposure - Postapplication	Cite-All	ARTF	PAY	
875.2500	Inhalation Exposure - Postapplication	Cite-All	ARTF	PAY	
Special	Exposure or Risk to Non-Target organisms	Cite-All	Generic Endangered Species Task Force	PAY	

Signature	Name and Title	Date
014074	Robert G. Butz,	7/28/2015
Holand S. Sunt	Authorized Agent for AgSaver II, LLC	
L'	Sullivan & Worcester LLP	ļ <i>•</i>

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DATA MATRIX			
Date: July 28, 2015	EPA Reg No./ File Symbol 85806-4	Page 14 of 14	
Applicant's/Registrant's Name and Address:  AgSaver II, LLC	Product:		
203 E. Ash Ave. McGehee, AR 71654	AgSaver Dicamba Technical		
Ingredient: Dicamba			

#### **End Notes**

1. This study is classified as an 875.2200 study in the Dicamba RED, but in NPIRS appears as an 875.2100 study. The study title also indicates it is probably an 875.2100 study.

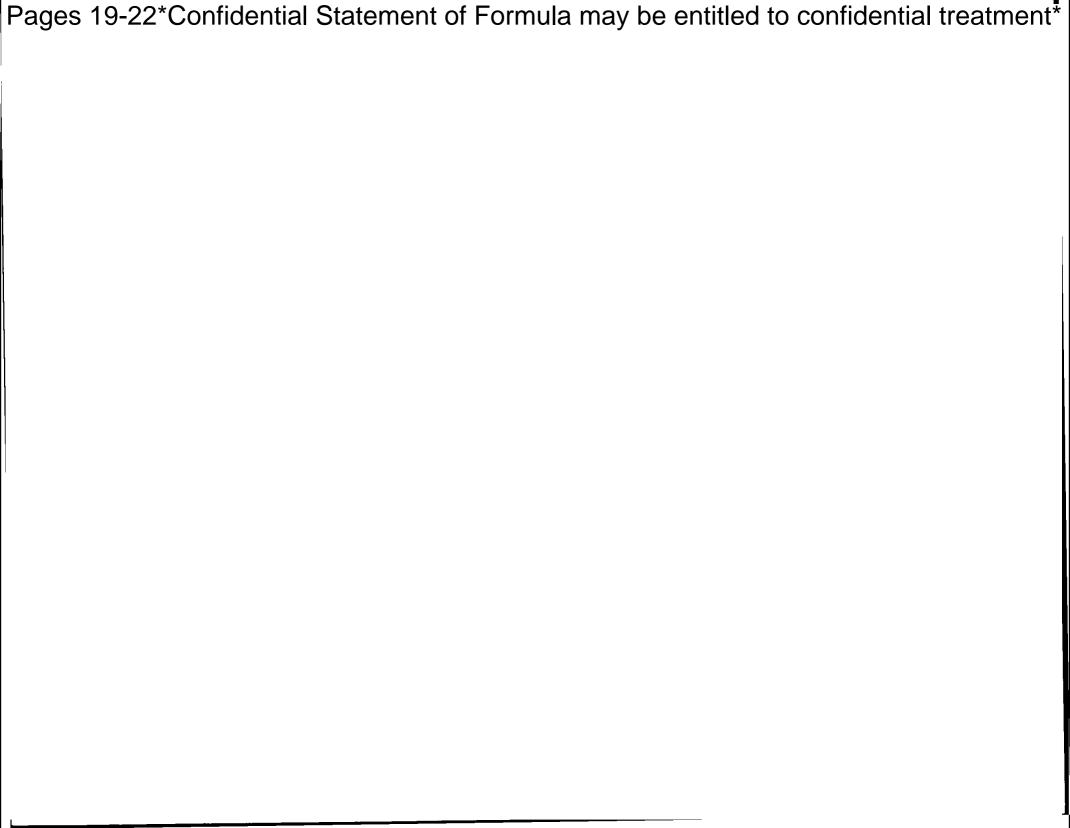
AgSaver II, LLC will make offers-to-pay to the following entities on the Data Submitters List of July 1, 2015:

- 1. AGRICULTURAL HANDLER EXPOSURE TASK FORCE
- 2. AGRICULTURAL REENTRY TASK FORCE
- 3. BASF CORPORATION
- 4. GENERIC ENDANGERED SPECIES TASK FORCE
- 5. SPRAY DRIFT TASK FORCE

Signatur-	Name and Title	Date
014074	Robert G. Butz,	7/28/2015
16 del S, Suit	Authorized Agent for AgSaver II, LLC	
<u> </u>	Sullivan & Worcester LLP	

6. SYNGENTA CROP PROTECTION, LLC

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## AgSaver™ Dicamba Technical FOR MANUFACTURING PURPOSES ONLY

Formulators who use this product are responsible for obtaining EPA registration for their formulated products.

## **ACTIVE INGREDIENT:** Dicamba (3,6-dichloro-o-anisic acid) .....

## KEEP OUT OF REACH OF CHILDREN **DANGER**

	FIRST AID
IF IN EYES:	<ul> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>Call a poison control center or doctor for treatment advice</li> </ul>
IF SWALLOWED:	<ul> <li>Call poison control center or doctor immediately for treatment advice.</li> <li>Have person sip a glass of water if able to swallow.</li> <li>Do not induce vomiting unless told to do so by the poison control center or doctor.</li> <li>Do not give anything by mouth to an unconscious person.</li> </ul>
IF ON SKIN OR CLOTHING:	<ul> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>
	HOT LINE NUMBER
	intainer or label with you when calling a poison control center or doctor, or going for also contact 1-800-222-1222 for emergency medical treatment information.
Probable mucosal	NOTE TO PHYSICIAN damage may contraindicate the use of gastric lavage.

See page [back] [side] [panel] [next page] for Directions for Use and for additional precautionary statements.

EPA Reg. No. 85806-4	EPA Est. No.
NET CONTENTS:	[Batch Code: to appear on label or container]

MANUFACTURED FOR: AgSaver™ II, LLC 203 East Ash Street • McGehee, AR 71654

## PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

**DANGER:** Corrosive. Causes irreversible eye damage. Harmful if swallowed. Do not get in eyes, on skin, or on clothing. Wear protective eyewear (goggles or face shield). Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

#### **ENVIRONMENTAL HAZARDS**

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your local State Water Board or Regional Office of the EPA.

### **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This technical material may only be used to produce formulations that are registered or exempted from registration by the U.S. EPA. If it is desired to produce formulations that do not have prior approval, the producer of such formulations is responsible for providing all necessary data and for obtaining registration.

Only for Formulation Into A Herbicide For (1) The Following Use(s): Asparagus, corn, fallow systems, grass forage, fodder and hay (including grasses grown for seed), millet, small grains (barley, oats, teff, wheat), sorghum (including Sudangrass), soybeans, sugarcane, cotton, pasture and rangeland, Conservation Reserve Program Areas, farmsteads, fence rows, non-irrigation ditchbanks, rights-of-way, roadsides, turf and sod farms; (2) Uses for which the U.S. EPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and (3) Uses for experimental purposes that are in compliance with U.S. EPA regulations.

This product may be used to formulate products for specific uses not listed or. the MP label if the formulator, user group, or grower has complied with U.S. EPA data submission requirements regarding support of such uses.

The user is solely responsible for determination of suitability of the use of this product for any specific purpose, any manufacturing practice employed, and adoption of such safety precautions as may be necessary.

### STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

**Pesticide Storage:** Store in original container in a well-ventilated area separately from fertilizer, feed and foodstuffs. Avoid cross-contamination with other pesticides. Spillage or leakage should be contained, carefully swept up and collected for disposal. Wash area of spill with detergent and water.

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

### Container Disposal: [[Nonrefillable Inner Liner]

Liner: Nonrefiliable container. Do not reuse or refill this bag. Completely empty removable liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by other procedures.] [and/or]

### [[Non-refillable Exterior Container]

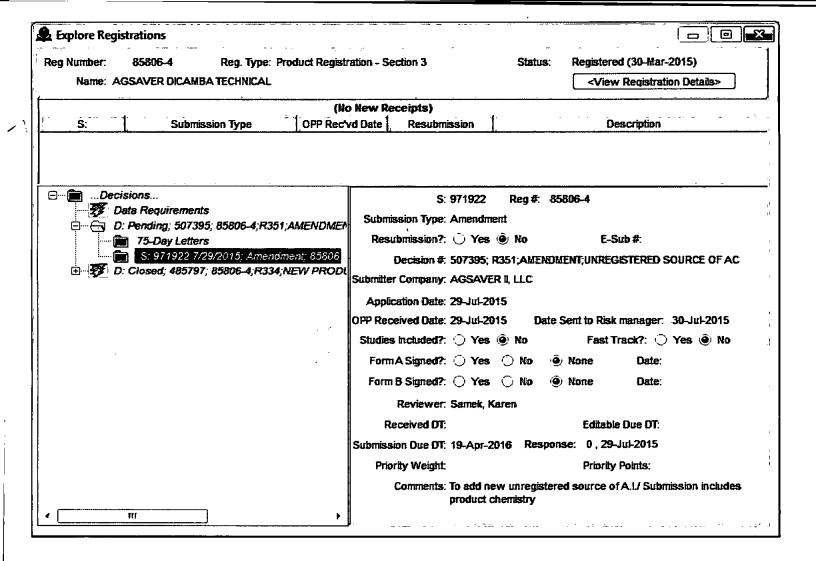
[Exterior Bag:] [OR] [Exterior Drum:] [Nonrefillable container. Do not reuse or refill this container. Completely empty removable liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into equipment. Then dispose of empty container in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by other procedures.]] [and/or]

### [[Refiliable Exterior Container]

[Exterior Bag:] [OR] [Exterior Drum:] [Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose. If container is contaminated or damaged, it cannot be reused. Completely empty container into equipment. Dispose of empty container in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by other procedures. Emptying the container before final disposal is the responsibility of the person disposing of the container.]

#### CONDITIONS OF SALE AND LIMITATION OF WARRANTY

Seller warrants that this product conforms with its specifications and is reasonably fit for the purposes stated on the label when used in accordance with its directions under normal conditions of use. To the extent permitted by applicable law buyer assumes the risk of any use contrary to such directions. Seller makes no other express or implied warranty of fitness or merchantability and no agent or reseller is authorized to do so except by Seller in writing with a specific reference to this warranty. To the extent consistent with applicable law, in no event shall Seller's liability for any breach of warranty exceed the purchase price of the material on which claim is made.



AUG 2 6 2015

## Herbicide Branch Assignment Sheet

**Product Managers** 

Kathryn Montague

PM 23

Date Delivered to PM

Reuben Baris

PM 25

	Risk Ma	<u>nagers</u>	
Beth	Shanta	Emily	Sarah
Grant	Mindy	Juanita	Terri
Karen	Deirdre	Dianne	Dominic
	to Summer/Eleand	P351	
Date to Sun	nmer / Eleanor	(m 8/25/15	5
Process His	tory		



### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

August 06, 2015

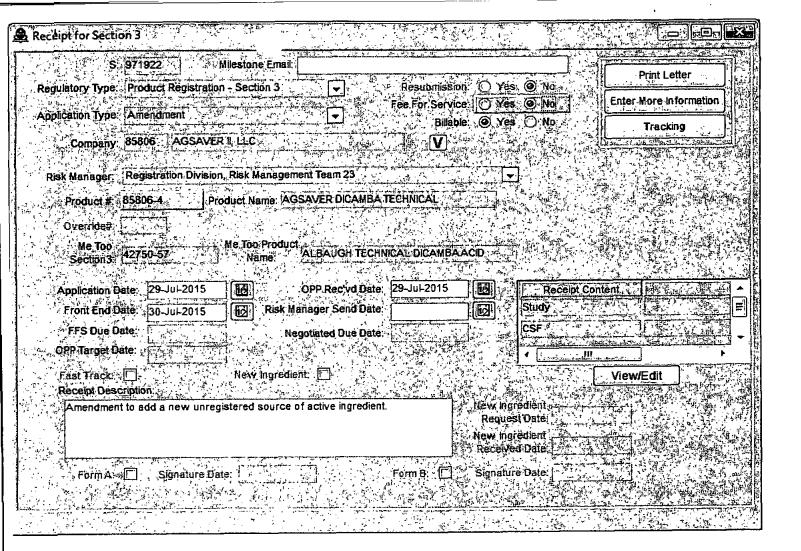
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

SULLIVAN & WORCESTER LLP AGSAVER II, LLC 1666 K STREET, NW SUITE 700 WASHINGTON, DC 20006

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 29-JUL-15. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.





Sullivan & Worcester LLP 1666 K Street, NW Washington, DC 20006 T 202 775 1200 F 202 293 2275 www.sandw.com

July 29, 2015

1

#### **CONTAINS CONFIDENTIAL BUSINESS INFORMATION**

Document Processing Desk (REGFEE)
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard Room S-4900
2777 S. Crystal Drive
Arlington, VA 22202

ATTN: Kathryn Montague, Product Manager #23

Re: <u>Amendment to add a new unregistered source of active ingredient for AgSaver™ Dicamba</u>
<u>Technical, EPA Reg. No. 85806-4</u>

Dear Ms. Montague:

On behalf of AGSAVER II, LLC, we are submitting an Amendment to add a new unregistered source of active ingredient for AgSaver™ Dicamba Technical, EPA Reg. No. 85806-4. This action falls under R351.

#### Please find attached:

- 1. Transmittal Document
- 2. Application Form (EPA Form 8570-1)
- 3. Confidential Statement of Formula, Alternate Formulation #1, dated 7/28/2015
- 4. Certification with Respect to Citation of Data, dated 7/28/2015 (Form 8570-34)
- 5. Data Matrix, dated 7/28/2015 (EPA Form 8570-35, Agency and Public Use)
- Copy of label (Label Code: ESL20150330 FPL20150620; W0277280)
- 7. 3 copies each of the study reports
- 8. A copy of the PRIA fee email receipt

If you have any questions regarding this submission, please do not hesitate to contact me.

Sincerely,

Janine Gydus

igydus@sandw.com

202-775-1235

**Enclosures** 

cc: Telisport W Putsavage, Sullivan & Worcester

Clarke Pugh, AgSaver II, LLC

#### TRANSMITTAL DOCUMENT

#### Submitter:

AgSaver II, LLC 203 East Ash Street McGehee, AR 71654

**EPA Company Number 85806** 

### **Company Contact:**

Joninemorgens

Janine M. Gydus, Staff Scientist/Authorized Agent

Sullivan & Worcester LLP

1666 K St. NW, Suite 700, Washington, DC 20006

Phone: 202-775-1235 Email Address: jgydus@sandw.com

### Regulatory Action in Support of Which this Package is Submitted:

Amendment to add source of active ingredient to AgSaver Dicamba Technical (85806-4)

## Submission Date:

7/29/2015

#### **List of Submitted Documents:**

	Description	MRID
Volume 1	Administrative Materials:	
	1. Application Form (Form 8570-1)	
	2. Confidential Statement of Formula, Alt Form #1 (Form 8570-4)	· ·
	3. Certification with Respect to Citation of Data (Form 8570-34)	
	4. Data Matrix (Form 8570-35, Agency and Public Use)	
	5. 3 copies each of enclosed reports	
	6. Label	
	7. Copy of PRIA fee payment email receipt	
Volume 2	Butz, R. 2015. AgSaver Dicamba Technical: Product Identity and	496 83601
	Composition, Description of Beginning Materials and Manufacturing	110-30-1
	Process, Discussion of Formation of Impurities, Certified Limits and	
	Analytical Method. OCSPP 830.1550, 830.1600, 830.1620, 830.1670,	
	830.1750, 830.1800. 71 pages.	
Volume 3	Sun, G. 2009. Preliminary Analysis of Dicamba Technical Grade Active	
	Ingredient. OCSPP 830.1700 & 830.1800. 48 pages.	44663602
Volume 4	Sun, G. 2015. Polychlorinated Dibenzodioxins and Polychlorinated	
	Dibenzofurans Analysis of Dicamba Technical Grade Active Ingredient.	49663603
	OCSPP 830.1700 & 830.1800. 123 pages.	
Volume 5	Miller, R. 2013. Physical and Chemical Characteristics of Dicamba 98%.	
	OCSPP 830.6302, 830.6303, 830.6304, 830.6313, 830.6314, 830.6317,	
	830.6320, 830.7000, 830.7050, 830.7200 & 830.7300. 72 pages.	49683604

## Memorandum

Date:8	3 / 12 / 201	<u>5</u>
To:	23	, Regulatory Manager
From: Info	ormation Servic	es Branch, ITRMD
	at MRIDs for the	a submission is not an he enclosed studies have
-	ove date befor	be approximately 5 days e the study-level data is
	ave any question of the contract of the contra	ons about this process, as (305-5363).
This is a:	-	ed submission cepted submission omission

Waiting for date

AB 8 | 13 | 15

## **21-Day Screen of Amendment** (Completed by Contractor)

21-day Expires on 8/19/15

Document Part Of: 85806-4 MRID, If Any: 496836

Content Screen: Recommended to Pass/Fail

11-3 Review: Passed/Failed/NA

Overall Status: Pass/Fail

Document returned to:

Steve Schaible

PRIA 3 – 21 Day Content Screen Review Worksheet
(EPA/OPP Use Only)
September 2012

21 Day Screen Start Date:	9/15				
Experts In-Processing Signature:		MP	Date 7/30/15	Fee Paid:	Yes
Division management contacted on issues	No	Yes_	Date		<del></del>

EPA	Reg. Number: 85806-4 EPA Receipt Date: 7	129/1				
	Items for Review			Yes	No	N/A*
1	Application Form (EPA Form 8570-1) signed & complete including type	ling pac	kage	Ϋ́		
4	Confidential Statement of Formula all boxes completed, form s dated (EPA Form 8570-4)	igned, a	nd	·χ		
2	a) All inerts, including fragrances, approved for the proposed uses (see Footnote A) w/a Tech 2 \mpu atte>	yes	no	, ,		, .
3	Certification with Respect to Citation of Data (EPA Form 8570 completed and signed (N/A if 100% repack)	)-34)		Ϋ́		,
	Certificate and data matrix consistent			, Х		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			<b>"</b>
	If applicable, is there a letter of Authorization for exclusive use of	nly.				
, 4	Formulator's Exemption Statement (EPA Form 8570-27) comparing signed (N/A if source is unregistered or applicant owns the technic		d ·			X
ı	Data Matrix (EPA Form 8570-35) both internal and external cop completed and signed (N/A if 100% repack)	ies ( <u>PR</u>	98-5)	X	•	
5	a) Selective Method (Fee category experts use)	yes	no	- 62	77.0	a Contract
	b) Cite-All (Fee category experts use)					
•	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of <u>Label</u> ( <u>Electronic labels on CD</u> are encouraged an available)	d guida	nce is	X		
7	Is the data package consistent with PR Notice 86-5			X		
8	Notice of Filing included with petitions					X

9	If applicable for conventional applications, reduced risk rationale		Х
	Required Data and/or data waivers. See Footnote C.		,
	a) List study (or studies) not included with application		
10			
10			
:			

#### Comments:

Documentation: Pass

The public matrix is missing.

the registrant insists that the public matirx was included who the original submission. This is not the 1st time this comment has been made by a registrant. It seems that jackets are consistantly being given to analysts to review where public matrix removed.

The registrant provided or new copy of the missing public via email.

Technical & impurities only, no inerts to review

11-3: Pass

MRID 496836

Status: Pass

#### **Footnotes**

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are strongly encouraged to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency even if a product is currently registered by consulting the inert Web site and if the inert is not approved nor has an application pending with the Agency, to obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at <a href="mailto:inertsbranch@epa.gov">inertsbranch@epa.gov</a> and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the <a href="mailto:Chief of Microbial Pesticides Branch">Chief of Microbial Pesticides Branch</a>.

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

#### **Unapproved Inerts Identified on CSFs**

#### All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

- Correct the application by, for instance, correcting the inert's identity or CAS
  number, providing documentation that the inert has been approved, or
  removing the unapproved inert from the CSF or replacing it with one that is
  approved for the application's uses; or
- 2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or
- 3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;
- 4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

#### Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

- 1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
- 2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

#### **PIP Applications**

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

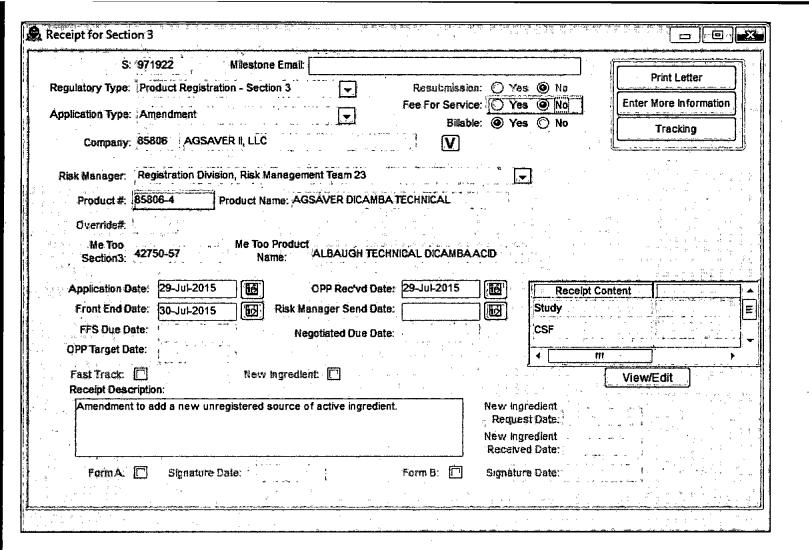
- 1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
- 2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.
- 3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

- B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.
- C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

## **Script for Rejection Phone calls**

First Call/Initials: 140  Date: 8/12/2015	Second Call/Initials:  Date:
Time: 11:26 AM	Time:
This is	, EPA contractor.
I'm calling regarding Dicamba Technica	your submission in support of (85804–4)
We have found the fo	llowing deficiencies regarding:
PR Notice 2011-3: Y Volume/Study	
Volume/Study	Title:
Volume/Study	Title:
Additional volu	imes continued on back of page: Yes or No
Application Package:	Yes or No
The public data	matrix is missing (corrections recid 8/
	ve been approved by EPA. be faxed to 703-305-5060/Attn:



Please read instructions on reven	se before completing form		For	m A			0-0060, Approval exp	
A ====	Unit	ted States			Registra		OPP Identif	ier Number
<b>\$EPA</b>	Environmental	Protection Ag	ency	<u>X</u>	Amendr Other	nent		
	Washing	ton, DC 20460	L		Other			
		olication for Pe	sticide – Section					
<ol> <li>Company/Product Number</li> <li>EPA File Symbol: 85806-4</li> </ol>	r		EPA Product Mai     Kathryn Montague	nag	ger	3. Pr	oposed Classificat	tion
4. Company/Product (Name)			PM#				None Re	estricted
AgSaver™ Dicamba Techni 5. Name and Address of App			23 6. Expedited Revie		In coord	لـــا ا	EIEBA Continu 2/	-N/2N
AGSAVER II, LLC	ilicant (Include ZIP Code)		(b)(i), my product is					
P. O. Box 111 MCGEHEE, AR 71654			to: EPA Reg No.					
Check if this is a new ac	ddress		Product Name					
		Saction	on – II		· · - ·-	· ·		
X Amendment – Explain b	elow	Section		lab	els in resp	onse to A	gency letter dated	
				_	ŕ		- •	
Resubmission in respon	se to Agency letter dated		"Me Too" App	plic	ation			
Notification – Explain be	elow		Other – Expla	ain	below			
Explanation: Use additional This action is PRIA Category	R351		ction II.) Amendment to	оа	idd a new u	nregister	ed source of active	e ingredient
Point of Contact: Robe	rt Butz <u>rbutz@sandw.cc</u>		on III				·-· -	-
1. Material This Product Will i	be Packaged in:							
Child-Resistant Packaging Yes	Unit Packaging Yes	Wa	ter Soluble Packaging 7 Yes	ı		2. T	ype of Container Metal	<del></del>
X No	X No	x				X	Plastic	
						$\square$	Glass	
*Certification must be submitted	If "Yes" Unit Packaging wgt.	1	Yes" ckage wgt		No. per container		Paper Other (Specify) _	
3. Location of Net Contents In X Label	nformation Container	4. Size(s) Retail	Container	J	5. L	On Labe		
6. Manner in Which Label is A	Affixed to Product	Lithograph		×	Other		el accompanying p	product
		X Paper glue Stenciled						
		Secti	on IV				<del>.</del>	
1. Contact Person (Complete	items directly below for it		idual to be contacted,	if r				
Name Robert G. Butz			Worcester LLP		20	elephone 02-775-12	No. (Include Area 211	Code)
I certify that the statements 1 h	ave made on this form and	rtification I all attachments the		an	d complete.		6. Date Application	tion
I acknowledge that any knowing both under applicable law	gly false or misleading sta	tement may be puni	shable by fine or impris	son	iment or			
2. Signature		3. Title					(Stamp	ed)
Rlut 2,	Bot		tist, Sullivan & Worce Agent for AgSaver II				•••	
4. Typed Name		5. Date					•••	_
Robert G. Butz		7/29/ 2015					••••	
EPA Form 8570-1 (Rev. 8-94)	Previous editions are obsol	lete.	White -	– E	PA File Cop	y (Origina	al) Yellow – App	licant Copy
							•••••	••••
							•	••••

Sullivan & Worcester LLP 1666 K Street, NW Washington, DC 20006 T 202 775 1200 F 202 293 2275 www.sandw.com

July 29, 2015

#### **CONTAINS CONFIDENTIAL BUSINESS INFORMATION**

Document Processing Desk (REGFEE)
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard Room S-4900
2777 S. Crystal Drive
Arlington, VA 22202

ATTN: Kathryn Montague, Product Manager #23

Re: <u>Amendment to add a new unregistered source of active ingredient for AgSaver™ Dicamba</u>
<u>Technical, EPA Reg. No. 85806-4</u>

Dear Ms. Montague:

On behalf of AGSAVER II, LLC, we are submitting an Amendment to add a new unregistered source of active ingredient for AgSaver™ Dicamba Technical, EPA Reg. No. 85806-4. This action falls under R351.

#### Please find attached:

- 1. Transmittal Document
- 2. Application Form (EPA Form 8570-1)
- 3. Confidential Statement of Formula, Alternate Formulation #1, dated 7/28/2015
- 4. Certification with Respect to Citation of Data, dated 7/28/2015 (Form 8570-34)
- 5. Data Matrix, dated 7/28/2015 (EPA Form 8570-35, Agency and Public Use)
- Copy of label (Label Code: ESL20150330 FPL20150620; W0277280)
- 7. 3 copies each of the study reports
- 8. A copy of the PRIA fee email receipt

If you have any questions regarding this submission, please do not hesitate to contact me.

Sincerely,

Janine Gydus

igydus@sandw.com

202-775-1235

**Enclosures** 

cc: Telisport W Putsavage, Sullivan & Worcester

Clarke Pugh, AgSaver II, LLC

### TRANSMITTAL DOCUMENT

#### **Submitter:**

AgSaver II, LLC 203 East Ash Street McGehee, AR 71654

**EPA Company Number 85806** 

### **Company Contact:**

General Golis

Janine M. Gydus, Staff Scientist/Authorized Agent

Sullivan & Worcester LLP

1666 K St. NW, Suite 700, Washington, DC 20006

Phone: 202-775-1235 Email Address: jgydus@sandw.com

### Regulatory Action in Support of Which this Package is Submitted:

Amendment to add source of active ingredient to AgSaver Dicamba Technical (85806-4)

## Submission Date: 7/29/2015

#### **List of Submitted Documents:**

	Description	MRID
Volume 1	Administrative Materials:	
	1. Application Form (Form 8570-1)	
	2. Confidential Statement of Formula, Alt Form #1 (Form 8570-4)	
	3. Certification with Respect to Citation of Data (Form 8570-34)	
	4. Data Matrix (Form 8570-35, Agency and Public Use)	
	5. 3 copies each of enclosed reports	
	6. Label	
	7. Copy of PRIA fee payment email receipt	
Volume 2	Butz, R. 2015. AgSaver Dicamba Technical: Product Identity and	
	Composition, Description of Beginning Materials and Manufacturing	
	Process, Discussion of Formation of Impurities, Certified Limits and	
	Analytical Method. OCSPP 830.1550, 830.1600, 830.1620, 830.1670,	
	830.1750, 830.1800. 71 pages.	
Volume 3	Sun, G. 2009. Preliminary Analysis of Dicamba Technical Grade Active	
	Ingredient. OCSPP 830.1700 & 830.1800. 48 pages.	
Volume 4	Sun, G. 2015. Polychlorinated Dibenzodioxins and Polychlorinated	
	Dibenzofurans Analysis of Dicamba Technical Grade Active Ingredient.	
	OCSPP 830.1700 & 830.1800. 123 pages.	
Volume 5	Miller, R. 2013. Physical and Chemical Characteristics of Dicamba 98%.	
÷	OCSPP 830.6302, 830.6303, 830.6304, 830.6313, 830.6314, 830.6317,	
	830.6320, 830.7000, 830.7050, 830.7200 & 830.7300. 72 pages.	



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20460. Do not send the completed form to this address.			
Certification with	Respect to Citatio	on of Data	
Applicant's/Registrant's Name, Address, and Telephone Number AGSAVER II, LLC 203 EAST ASH STREET MCGEHEE AR 71654		EPA Registration Number/File S 85806-4	Symbol
Active Ingredient(s) and/or representative test compound(s) Dicamba, CAS Reg. No. 1918-00-9		Date July 28, 2015	
General Use Pattern(s) (list all those claimed for this product using 40 C Terrestrial Food Crop; Terrestrial Nonfood Crop, Terrestrial Noncre EPA has accepted required data and/or citations of data in support uses for experimental purposes in compliance with US EPA.	op uses for which U		
<b>NOTE</b> : If your product is a 100% repackaging of another purchased EF to submit this form. You must submit the Formulators Exemption States	PA-registered product ment (EPA Form 857	labeled for all the same uses on you 0-27)	ur label, you do not need
I am responding to a Data-Call-In Notice, and have included w should be used for this purpose).	ith this form a list of c	ompanies sent offers of compensati	on (the Data Matrix form
SECTION I: METHOD OF DA	TA SUPPORT (Chec	k one method only)	
I am using the cite-all method of support, and have included w this form a list of companies sent offers of compensation (the I Matrix form should be used for this purpose)	Data X ui	am using the selective method of sup nder the selective method), and have completed list of data requirements ust be used).	included with this form
SECTION II: G	ENERAL OFFER TO	PAY	
[Required if using the cite-all method, or when using the cite-all option $\boldsymbol{\boldsymbol{u}}$	ınder the selective m	ethod to satisfy one or more data req	uirements]
I hereby offer and agree to pay compensation, to other person	s, with regard to the a	approval of this application, to the ex	tent required by FIFRA
SECTION	III: CERTIFICATION		
I certify that this application for registration, this form for reregist the application for registration, the form for reregistration, or the Data-C selective method is indicated in Section 1, this application is supported product or an identical or substantially similar product, or one or more obe submitted under the data requirements in effect on the date of approidentical or similar composition and uses.	all-In response. In ad by all data in the Age f the ingredients in th	dition, if the cite-all option or cite-all once it in the prope is product; and (2) is a type of data to	option under the orties or effects of this hat would be required to
I certify that for each exclusive use study cited in support of this obtained the written permission of the original data submitted to cite that		stration, that I am the original data su	ubmitter or that I have
I certify that for each study cited in support of this registration or submitter; (b) I have obtained the permission of the original data submit compensation have expired for the study; (d) the study is in the public li have offered (i) to pay compensation to the extent required by sections determine the amount and terms of compensation, if any, to be paid for	ter to use the study ir terature; or (e) I have 3(c)(1)(F) and/or 3(c)	n support of this application; (c) all pe notified in writing the company that	eriods of eligibility for submitted the study and see segotiations to
I certify that in all instances where an offer of compensation is reaccordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are avail such evidence to the Agency upon request, I understand that the Agency conformity with FIFRA.	equired, copies of all lable and will be subr	nitted to the Agency upon request. S	Should I fail to preduce •
I certify that the statements I have made on this form and al knowingly false or misleading statement may be punishable by fine			acknowledge that any
Signature	Date	Typed or Printed Name and Title	·····
Clarke Bh	7/28/2015	Clarke Pugh, Member, AgSaver II, LLC	•

EPA Form 8570-34 (9-97) Electronic and Paper versions available. Submit only Paper version.



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

July 30, 2015

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

OPP Decision Number: D-507395

EPA File Symbol or Registration Number: 85806-4 Product Name: AGSAVER DICAMBA TECHNICAL

EPA Receipt Date: 29-Jul-2015 EPA Company Number: 85806

Company Name: AGSAVER II, LLC

ROBERT G. BUTZ, PH.D.
SULLIVAN & WORCESTER LLP
AGSAVER II, LLC
1666 K STREET, NW SUITE 700
WASHINGTON, DC 20006-

SUBJECT: Receipt of Registration Amendment Subject to Registration Service Fee

### Dear Registrant:

The Office of Pesticide Programs has received your amendment and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R351

AMENDMENT; UNREGISTERED SOURCE OF ACTIVE INGREDIENT;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

Front End Processing Staff

Information Technology & Resources Management Division

## Fee for Service

{971922(~

This package includes the following	for Division
<ul><li>New Registration</li><li>Amendment</li></ul>	○ AD ○ BPPD ○ RD
<ul><li>Studies? □ Fee Waiver?</li><li>□ volpay % Reduction:</li></ul>	Risk Mgr. 23
Receipt No. S- EPA File Symbol/Reg. No. Pin-Punch Date:	971922 85806-4 7/29/2015
This item is NOT subject to	FFS action.
Action Code:  Requested: R351  Granted: R 351  Amount Due: \$ 12,596	Parent/Child Decisions:
Inert Cleared for Intended Use  Reviewer: Wayan K. Muhanned  Remarks:	Uncleared Inert in Product Date: 4/30(15

### Butz, Ph.D., Robert G.

From:

Clarke Pugh <clarkepugh@yahoo.com>

Sent:

Monday, June 22, 2015 1:07 PM

To:

Butz, Ph.D., Robert G.

Subject:

Fw: Pay.gov Payment Confirmation: PRIA Service Fees

---- Forwarded Message -----

From: "notification@pay.gov" <notification@pay.gov>

To: clarkepugh@yahoo.com

Sent: Monday, June 22, 2015 12:06 PM

Subject: Pay gov Payment Confirmation: PRIA Service Fees

Your payment has been submitted to Pay.gov and the details are below. If you have any questions regarding this payment, please contact Michael Yanchulis at (703) 347-0237 or <a href="mailto:yanchulis.michael@epa.gov">yanchulis.michael@epa.gov</a>.

Application Name: PRIA Service Fees Pay.gov Tracking ID: 25LV7DRN Agency Tracking ID: 74825588361

Transaction Type: Sale

Transaction Date: 06/22/2015 01:06:12 PM EDT

Account Holder Name: Clarke Pugh

Transaction Amount: \$12,596.00 Billing Address: PO Box 121

City: McGehee State/Province: AR Zip/Postal Code: 71654

Country: USA

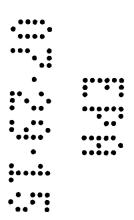
Card Type: AmericanExpress Card Number: \*\*\*\*\*\*\*7008

Registration Number: 85806-4 Company Name: AgSaver, LLC

Company Number: 85806

Action Code: R351

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.





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WASHINGTON, D.C. 20460

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## Date: July 28 2015 Applicant's/Registrant's Name and Address: AgSaver II, LLC 203 E. Ash Ave. McGehee, AR 71654 Ingredient: Dicamba EPA Reg No./ File Symbol 85806-4 Page 1 of 14 AgSaver Dicamba Page 1 of 14 AgSaver Dicamba

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			AgSaver II, LLC	OWN	
			AgSaver II, LLC	OWN	
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			AgSaver II, LLC	OWN	
			AgSaver II, LLC	OWN	
			AgSaver II, LLC	OWN	

Signature

Name and Title
Robert G. Butz,
Authorized Agent for AgSaver II, LLC
Sullivan & Worcester LLP

Name and Title
Robert G. Butz,
Authorized Agent for AgSaver II, LLC

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version. {W0277296; 1}



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WASHINGTON, D.C. 20460

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## Date: July 28 2015 Applicant's/Registrant's Name and Address: AgSaver II, LLC 203 E. Ash Ave. McGehee, AR 71654 Ingredient: Dicamba EPA Reg No./ File Symbol 85806-4 Page 2 of 14 AgSaver Dicamba Page 2 of 14 AgSaver Dicamba

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			AgSaver II, LLC	OWN	
			AgSaver II, LLC	OWN	
			AgSaver II, LLC	OWN	
			AgSaver II, LLC	OWN	
			AgSaver II, LLC	OWN	
			AgSaver II, LLC	OWN	
			AgSaver II, LLC	N/A	N/A per 830.1000
			AgSaver II, LLC	N/A	N/A per 830.1000
			AgSaver II, LLC	OWN	1
			AgSaver II, LLC	OWN	
			AgSaver II, LLC	OWN .	
			AgSaver II, LLC AgSaver II, LLC	OWN ·	
Signature Rut 8,	But		Name and Title Robert G. Butz, Authorized Agent for AgSaver II, Sullivan & Worcester LLP	•	Date . 7/28/2015

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version. {W0277296; 1}



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

WASHINGTON, D.C. 20460

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## Date: July 28 2015 Applicant's/Registrant's Name and Address: AgSaver II, LLC 203 E. Ash Ave. McGehee, AR 71654 Ingredient: Dicamba EPA Reg No./ File Symbol 85806-4 Product: AgSaver Dicamba Technical

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			AgSaver II, LLC	OWN	
			AgSaver II, LLC	OWN	•
			SANDOZ AGRO INC,	OLD	
			SANDOZ AGRO INC	OLD	
			ALBAUGH INC	OLD	
			SANDOZ AGRO INC	OLD	
			VELSICOL CHEMICAL CORP	OLD	
			ALBAUGH INC	OLD	
			VELSICOL CHEMICAL CORP	OLD	
			ALBAUGH INC	OLD	
			VELSICOL CHEMICAL CORP	OLD	
			Sandoz Agro, Inc.	OLD	
			Sandoz Agro, Inc.	OLD	
			Sandoz Crop Prot. Corp.	OLD	

Signature	•		Name and Title	Date
11 40	7 1-		Robert G. Butz,	7/28/2015
Helant S,	Sul		Authorized Agent for AgSaver II, LLC	
, =	- 1	•	Sullivan & Worcester LLP	

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## Date: July 28 2015 Applicant's/Registrant's Name and Address: AgSaver II, LLC 203 E. Ash Ave. McGehee, AR 71654 Ingredient: Dicamba EPA Reg No./ File Symbol Page 4 of 14 Page 4 of 14 AgSaver Dicamba Product: AgSaver Dicamba Technical

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Velsicol Chemical Corporation,	OLD	
			Sandoz Agro, Inc	OLD	
			Sandoz Agro, Inc	OLD	
			Sandoz Agro. Inc	OLD	
			Sandoz Agro. Inc	OLD	
			Sandoz Agro. Inc	OLD	
			Sandoz Agro. Inc	OLD	
			Sandoz Agro, Inc. Sandoz Agro, Inc. UNKNOWN	OLD OLD OLD	
			MONSANTO U.S. EPA	PL PL	
			Spray Drift Task Force	PAY	<del>.</del>

Signature .		•	Name and Title	Date
11 50	7 1-		Robert G. Butz,	7/28/2015
Helant S.	Sant		Authorized Agent for AgSaver II, LLC	
,		•	Sullivan & Worcester LLP	

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## Date: July 28 2015 Applicant's/Registrant's Name and Address: AgSaver II, LLC 203 E. Ash Ave. McGehee, AR 71654 Ingredient: Dicamba EPA Reg No./ File Symbol 85806-4 Product: AgSaver Dicamba Technical

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Spray Drift Task Force	PAY	
			VELSICOL CHEMICAL CORP	OLD	
			U.S. FISH & WILDLIFE	PL	
			U.S. EPA	OLD	
			VELSICOL CHEMICAL CORP	OLD	
		- ·	VELSICOL CHEMICAL CORP	OLD	***
<del>-</del>	-	<del></del>	US Fish & Wildlife Service	PL	
			VELSICOL CHEMICAL CORP	OLD	
			VELSICOL CHEMICAL CORP	OLD	
			VELSICOL CHEMICAL CORP U.S. EPA	OLD PL	
			SANDOZ AGRO INC	OLD OLD	
Signature  Relat 9	s, But		Name and Title Robert G. Butz, Authorized Agent for AgSaver I	I, LLC	Date 7/28/2015

Sullivan & Worcester LLP

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# DATA MATRIX Date: July 28 2015 Applicant's/Registrant's Name and Address: AgSaver II, LLC 203 E. Ash Ave. McGehee, AR 71654 Ingredient: Dicamba DATA MATRIX EPA Reg No./ File Symbol 85806-4 Page 6 of 14 85806-4 AgSaver Dicamba Technical

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			SANDOZ AGRO INC	OLD	•
			SANDOZ AGRO INC	OLD	
			SANDOZ AGRO INC	OLD	
			ENIMONT AMERICA, INC	OLD	
			SANDOZ AGRO INC	OLD	
			SANDOZ AGRO INC	OLD	
			BASF CORPORATION	PAY	
			BASE CORPORATION	PAY	
			BASE CORPORATION	PAY	<u>-</u>
			U.S. EPA	PL.	<del> </del>
			SANDOZ AGRO INC SANDOZ AGRO INC	OLD OLD	

Relat S. But

Name and Title
Robert G. Butz,
Authorized Agent for AgSaver II, LLC
Sullivan & Worcester LLP

7/28/2015

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			SANDOZ AGRO INC	OLD	
			SANDOZ AGRO INC	OLD	
			SANDOZ AGRO INC	OLD	
			SANDOZ AGRAO INC	OLD	
			WELLMARK INTERNATIONAL	OLD	
			SANDOZ AGRO INC	OLD	
			SANDOZ AGRO INC	OLD	
			SANDOZ AGRO INC	OLD	
			SANDOZ AGRO INC	OLD	
			SANDOZ AGRO INC	OLD	
			SANDOZ AGRO INC	OLD	
			SANDOZ AGRO INC	OLD	
			SANDOZ AGRO INC	OLD	
			SANDOZ AGRO INC	OLD	
			SANDOZ AGRO INC	OLD	
			WELLMARK INTERNATIONAL	OLD	
Signature		•	Name and Title	• ,	Date
101.50	7 /		Robert G. Butz,		7/28/2015
116 Land S,	Sul	•	Authorized Agent for AgSaver I	I, LLC	
/ -	- 1		Sullivan & Worcester LLP		

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## Date: July 28 2015 Applicant's/Registrant's Name and Address: AgSaver II, LLC 203 E. Ash Ave. McGehee, AR 71654 Ingredient: Dicamba EPA Reg No./ File Symbol Page 8 of 14 Page 8 of 14 AgSaver Dicamba

Guideline Reference	Guideline Study Name	MRID	Submitter	Status	Note
Number		Number	SANDOZ AGRO INC	OLD	}
			SANDOZ AGRO INC	OLD	
			SANDOZ AGRO INC	OLD	
			SANDOZ AGRO INC	OLD	1
			SANDOZ AGRO INC	OLD	
			SANDOZ AGRO INC	OLD	
			SANDOZ AGRO INC	OLD	i
			BASE CORPORATION	PAY	
			BASF CORPORATION	PAY	
			BASE CORPORATION	PAY	
			SANDOZ AGRO INC	OLD	
			BASF CORP	PAY	
				GAP	RED
			BASF CORP	PAY	
				GAP	RED
				GAP	RED
			VELSICOL CHEMICAL CORP	OLD	
gnature · .	•	•	Name and Title		· Date
11 +0	7 4		Robert G. Butz,		7/28/2019
Kelent S,	Dat "		Authorized Agent for AgSaver	II, LLC	
	- L		Sullivan & Worcester LLP		

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			VELSICOL CHEMICAL CORP	OLD	
			VELSICOL CHEMICAL CORP	OLD	
			VELSICOL CHEMICAL COR	OLD .	
			SANDOZ AGRO INC	OLD	
			SANDOZ AGRO INC	OLD	
			BASF CORPORATION	PAY	
_ <del>_</del> _			SANDOZ AGRO INC	OLD	
			SANDOZ AGRO INC SANDOZ AGRO INC	OLD OLD	
			SANDOZ AGRO INC SANDOZ AGRO INC	OLD OLD	
			VELSICOL CHEMICAL CORP SANDOZ AGRO INC	OLD OLD	
			SANDOZ AGRO INC	OLD	

Signature  Relate S. Bat	Name and Title Robert G. Butz, Authorized Agent for AgSaver II, LLC	Date 7/28/2015
	Sullivan & Worcester LLP	

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		<u>-</u>	SANDOZ AGRO INC	OLD	
			SANDOZ AGRO INC	OLD	
			INTERREGIONAL RESEARCH PROJECT NO. 4 (IR-4)	PL	
			SANDOZ AGRO INC	OLD	
			SANDOZ AGRO INC	OLD	
			SANDOZ AGRO INC	OLD	
			SANDOZ AGRO INC SANDOZ AGRO INC	OLD OLD	
			U.S. EPA	PL	
			SANDOZ WELLMARK INTERNATIONAL	OLD OLD	
			VELSICOL CHEMICAL CORP	OLD	RED
Signature  NL+ 2	R		Name and Title Robert G. Butz, Authorized Agent for AgSaver I	LUC	Date 7/28/2015

Sullivan & Worcester LLP

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			UNKNOWN	OLD	RED
			UNKNOWN	OLD	RED
			UNKNOWN	OLD	RED
			UNKNOWN	OLD	RED
			UNKNOWN	OLD	RED
			BASF CORPORATION	OLD	
			BASF CORPORATION	OLD	Ī
			SANDOZ AGRO INC BASF CORPORATION	OLD OLD	
			U.S. EPA	PL	
			Velsicol Chemical Corp.	OLD	
			SANDOZ AGRO INC	OLD	
			SANDOZ AGRO INC	OLD	
Signature Ref. 8,	But	•	Name and Title Robert G. Butz, Authorized Agent for AgSaver	II, LLC	Date 7/28/2015

Sullivan & Worcester LLP

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			SANDOZ AGRO INC	OLD	-
			E. I. DUPONT DE NEMOURS	OLD	
			SANDOZ AGRO INC	OLD	
			SANDOZ AGRO INC	OLD	
			SANDOZ AGRO INC	OLD	
			E. I. DUPONT DE NEMOURS	OLD	
	<u> </u>		SANDOZ AGRO INC	OLD	
			SANDOZ AGRO INC	OLD	
			VELSICOL CHEMICAL CORP	OLD	
		<del></del> -	VELSICOL CHEMICAL CORP	OLD	
			BASF CORPORATION	OLD	
			BASF CORP	PAY	

Signature	•		•	Name and Title	. Date
171	40	フル		Robert G. Butz,	7/28/2015
Ilakan	7 3,	Sut		Authorized Agent for AgSaver II, LLC	
, –		[		Sullivan & Worcester LLP	1

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
·-			AHETF	PAY	
			AHETF	PAY	
			ARTF, AHETF	PAY	
			ARTF. AHETF	PAY	
· · · .			U.S. EPA	PL	, , , _ , , , , , , , , , , , , , , , ,
			ARTF	PAY	
<u>.</u>			SYNGENTA CROP PROTECTION, LLC U.S. EPA	PAY PL	RED <sup>1</sup>
			ARTF	PAY	
- · · · · · · · · · · · · · · · · · · ·			ARTF	PAY	
			Generic Endangered Species Task Force	PAY	

Signature ·	•	•	Name and Title	Date
Rest S.	But.		Robert G. Butz, Authorized Agent for AgSaver II, LLC Sullivan & Worcester LLP	7/28/2015

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DATA MATRIX					
Date: July 28 2015	EPA Reg No./ File Symbol 85806-4	Page 14 of 14			
Applicant's/Registrant's Name and Address:  AgSaver II, LLC	Product:				
203 E. Ash Ave. McGehee, AR 71654	AgSaver Dicamba Technical				
Ingredient: Dicamba					

#### **End Notes**

1. This study is classified as an 875.2200 study in the Dicamba RED, but in NPIRS appears as an 875.2100 study. The study title also indicates it is probably an 875.2100 study.

AgSaver II, LLC will make offers-to-pay to the following entities on the Data Submitters List of July 1, 2015:

- 1. AGRICULTURAL HANDLER EXPOSURE TASK FORCE
- 2. AGRICULTURAL REENTRY TASK FORCE
- 3. BASE CORPORATION
- 4. GENERIC ENDANGERED SPECIES TASK FORCE
- 5. SPRAY DRIFT TASK FORCE

6. SYNGENTA CROP PROTECTION, LLC

Signature		Name and Title	Date
11 40		 Robert G. Butz,	7/28/2015
Heland >	S, Suit	Authorized Agent for AgSaver II, LLC	
,		Sullivan & Worcester LLP	

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## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DP BARCODE No.: <u>D429490</u>; FILE SYMBOL No.: <u>85806-4 (altCSF#1 screen)</u>; PRODUCT NAME: <u>Agsaver Dicamba Technical</u>; <u>DECISION No.: 507395</u>; PC Code(s): <u>029801</u>; ACTION CODE: <u>R351</u>; FOOD Use: <u>Yes</u>

DATE OUT: October 9, 2015

SUBJECT: Revised Completeness check screening for technical product "Agsaver Dicamba Technical"

FROM: Shyam Mathur,

**Product Chemistry Team Leader** 

CITAB / RD (7505P)

TO: Karen Samek / Kathryn Montague, RM 23

Herbicide Branch / RD (7505P)

Company Name: Agsaver II, LLC Formulation Type: Herbicide

Active Ingredient(s): Dicamba (98.75%)

MRID Nos: Submitted - 49683601 to 49683604

CONCLUSION:

Deficiencies: No

(if there are deficiencies they are indicated below each heading as Note 1, Note 2 Etc).

Group A: All required data submitted

Group B: All required data submitted or cited

CSF: Current Basic CSF (dated 02-09-2015; Producer:

Proposed alternate CSF #1 (dated 07-25-2015; Producer -

submitted

Product label: Not Submitted

Note to PM: If the deficiencies are found in the screen results, please inform the registrant and bring back to author of this report the corrected deficiencies in response to 10 day letter, so that it can be attached to the original bean, if the data package is still in CITAB. New Bean is required in case the bean has been closed by CITAB. Thank you.

\*Product ingredient source information may be entitled to confidential treatment\*

### Samek, Karen

From:

Mathur, Shyam

Sent: To: Friday, October 09, 2015 1:36 PM Samek, Karen; Montague, Kathryn V.

Subject:

45/90 day screen results for 85806-4

Attachments:

85806-4 (altCSF#1 screen).doc

Shyam Mathur, Ph. D Product Chemistry Team Leader Chemistry, Inert & Toxicology Assessment Branch (CITAB)/RD (7505P) OCSPP/Environmental Protection Agency, USA Tel: 703-308-9374

Tel: 703-308-9374 mathur.shyam@epa.gov

## PROCESSING REQUEST

Reg #: 85806- Decision #: 485/9/
Description: New Product
Material Available Electronically (see PPLS):
Electronic Label/Letter Dated:
Other:
Material Sent (see jacket):
Stamped Label/Letter Dated:
Notification Dated:
☐ New CSF(s) Dated:
Other:
File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.
Reviewer: Grant Rowland
Division: RN/HB
Phone: 3-17-0254 Date: 3-31/5



#### U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs Registration Division (7505P) 1200 Pennsylvania Ave., N.W. Washington, D.C. 20460

#### NOTICE OF PESTICIDE:

X Registration
Reregistration
(under FIFRA, as amended)

EPA	Reg.	Number	٠

Date of Issuance:

85806-4

3/30/15

Term of Issuance:

Unconditional

Name of Pesticide Product:

AgSaver ™ Dicamba Technical

Name and Address of Registrant (include ZIP Code):

AgSaver II, LLC P.O. Box 111 McGehee, AR 71654

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is unconditionally registered in accordance with FIFRA section 3(c)(5) provided that you:

- 1. Submit and/or cite all data required for registration/registration/registration review of your product when the Agency requires all registrants of similar products to submit such data.
- 2. Make the following label changes before you release the product for shipment:
  - Revise the EPA Registration Number to read, "EPA Reg. No. 85806-4."
- 3. Submit one copy of the revised final printed label for the record before you release the product for shipment.

Signature of Approving Official:	Date:
Paytryn V. W Tontaguo	3/30/15
Kathryn Montague, Product Manager 23	
Herbicide Branch	
Registration Division (7505P)	

EPA Form 8570-6

Page 2 of 2 EPA Reg. No. 85806-4 Decision No. 485797

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

Basic CSF dated 02/9/2015

If you have any questions, please contact Grant Rowland by phone at 703-347-0254, or via email at Rowland.Grant@epa.gov.

Sincerely,

Kathryn V. Montague, Product Manager 23

Herbicide Branch

Registration Division (7505P) Office of Pesticide Programs

**Enclosure** 

Draft Label EPA 20131126 rev.20141919

Reviewer: Text in brackets [] are optional and may not appear on final printed label.

### ACCEPTED

03/30/2015

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 95906

85806-4

### AgSaver™ Dicamba Technical FOR MANUFACTURING PURPOSES ONLY

Formulators who use this product are responsible for obtaining EPA registration for their formulated products.

ACTIVE INGREDIENT:		
Dicamba (3,6-dichloro-o-anisic acid)	,	98.9%
OTHER INGREDIENTS:		1.1%
	TOTAL	

### KEEP OUT OF REACH OF CHILDREN DANGER

FIRST AID				
IF IN EYES:	<ul> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>Call a poison control center or doctor for treatment advice</li> </ul>			
IF SWALLOWED:	<ul> <li>Call poison control center or doctor immediately for treatment advice.</li> <li>Have person sip a glass of water if able to swallow.</li> <li>Do not induce vomiting unless told to do so by the poison control center or doctor.</li> <li>Do not give anything by mouth to an unconscious person.</li> </ul>			
IF ON SKIN OR CLOTHING:	<ul> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>			
	HOT LINE NUMBER			
	ntainer or label with you when calling a poison control center or doctor, or going for also contact 1-800-222-1222 for emergency medical treatment information.			
Probable mucosal of	NOTE TO PHYSICIAN damage may contraindicate the use of gastric lavage.			

See page [back] [side] [panel] [next page] for Directions for Use and for additional precautionary statements.

EPA Reg. No. 85806-	•	EPA Est. No.
NET CONTENTS:		[Batch Code: to appear on label or container]

MANUFACTURED FOR: AgSaver™ II, LLC 203 East Ash Street • McGehee, AR 71654

1

{W0271188; 1}

Reviewer: Text in brackets [] are optional and may not appear on final printed label.

## PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

**DANGER:** Corrosive. Causes irreversible eye damage. Harmful if swallowed. Do not get in eyes, on skin, or on clothing. Wear protective eyewear (goggles or face shield). Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

#### **ENVIRONMENTAL HAZARDS**

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your local State Water Board or Regional Office of the EPA.

#### **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This technical material may only be used to produce formulations that are registered or exempted from registration by the U.S. EPA. If it is desired to produce formulations that do not have prior approval, the producer of such formulations is responsible for providing all necessary data and for obtaining registration.

Only for Formulation Into A Herbicide For (1) The Following Use(s): Asparagus, corn, fallow systems, grass forage, fodder and hay (including grasses grown for seed), millet, small grains (barley, oats, teff, wheat), sorghum (including sudangrass), soybeans, sugarcane, cotton, pasture and rangeland, Conservation Reserve Program Areas, farmsteads, fence rows, non-irrigation ditchbanks, rights-of-way, roadsides, turf and sod farms; (2) Uses for which the U.S. EPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and (3) Uses for experimental purposes that are in compliance with U.S. EPA regulations.

This product may be used to formulate products for specific uses not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA data submission requirements regarding support of such uses.

The user is solely responsible for determination of suitability of the use of this product for any specific purpose, any manufacturing practice employed, and adoption of such safety precautions as may be necessary.

Reviewer: Text in brackets [] are optional and may not appear on final printed label.

#### STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

**Pesticide Storage:** Store in original container in a well-ventilated area separately from fertilizer, feed and foodstuffs. Avoid cross-contamination with other pesticides. Spillage or leakage should be contained, carefully swept up and collected for disposal. Wash area of spill with detergent and water.

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

### Container Disposal: [[Nonrefillable Inner Liner]

Liner: Nonrefillable container. Do not reuse or refill this bag. Completely empty removable liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by other procedures.] [and/or]

#### [[Non-refillable Exterior Container]

[Exterior Bag:] [OR] [Exterior Drum:] [Nonrefillable container. Do not reuse or refill this container. Completely empty removable liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into equipment. Then dispose of empty container in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by other procedures.]] [and/ or]

#### [[Refillable Exterior Container]

[Exterior Bag:] [OR] [Exterior Drum:] [Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose. If container is contaminated or damaged, it cannot be reused. Completely empty container into equipment. Dispose of empty container in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by other procedures. Emptying the container before final disposal is the responsibility of the person disposing of the container.]

#### **CONDITIONS OF SALE AND LIMITATION OF WARRANTY**

Seller warrants that this product conforms with its specifications and is reasonably fit for the purposes stated on the label when used in accordance with its directions under normal conditions of use. To the extent permitted by applicable law buyer assumes the risk of any use contrary to such directions. Seller makes no other express or implied warranty of fitness or merchantability and no agent or reseller is authorized to do so except by Seller in writing with a specific reference to this warranty. To the extent consistent with applicable law, in no event shall Seller's liability for any breach of warranty exceed the purchase price of the material on which claim is made.



#### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460



OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS **REGISTRATION DIVISION (7505P)** 

**DECISION No.: 485797** 

DP BARCODE No.: D425660

PC CODE: 029801

FOOD USE: No

FILE SYMBOL NO.: 85806-U

**ACTION CODE: R 334** 

PRODUCT NAME: AgSaver Dicamba Herbicide

DATE OUT:

March 23, 2015

SUBJECT:

Manufacturing Use Product Chemistry Review

Product Name: AgSaver Dicamba Technical

FROM:

Bruce F. Kitchens, Chemist Product Chemistry Team

Bruce 7. Kathers 24 Mar 2015 Bru 8(26/1) Chemistry, Inerts and Toxicology Assessment Branch/RD (7505P)

TO:

RM 23, Kathryn V. Montague/Grant Rowland

Herbicide Branch/RD (7505P)

#### INTRODUCTION:

The registrant, AgSaver II, LLC, is responding to a previous product chemistry review (D417765 8/21/14) for the proposed manufacturing use product, AgSaver Dicamba Technical. In that review, it was determined that the data requirements for product identity and composition (830-1550), discussion of the formation of impurities (830.1670), and preliminary analysis (830.1700) were not satisfied. Additional data regarding the impurity profile was required. Also a discrepancy in the reported density value required clarification. The active ingredient in this product is Dicamba at a label nominal concentration of 98.9% a.i. This product is intended for use as in the manufacture of herbicide end-use products. With this response, the registrant is submitting product chemistry data contained in MRID# 495651-01. The Chemistry, Inerts and Toxicology Assessment Branch (CITAB) has been asked to review this submission.

#### **SUMMARY OF FINDINGS:**

1. Name of Active Ingredient:

Dicamba (98.90% ai)

Formulation Type:

Powder

2. The registrant submitted the following study:

Sun, G., Polychlorinated Dibenzodioxins and Polychlorinated Dibenzofurans Analysis of Dicamba TGAI (2015), Performing Laboratory: Southwest Research Institute, Project # 01.20881.01.001, Sponsor: USA AG Chemicals Incorporated, MRID# 495651-01.

3. The registrant states that this study was conducted in accordance with 40 CFR 160 Good Laboratory Practices Standards and was inspected by the quality assurance unit

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PRODUCT NAME: AgSaver Dicamba Herbicide

**DECISION No.: 485797** 

4. This study is intended to determine the polychlorinated dibenzodioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs) in Dicamba technical present at or above the concentration of 0.1part per billion. Analyses of the samples was determined by high resolution gas chromatograph (HRGC)/high resolution mass spectrometer (HRMS). This method was validated for linearity, precision, accuracy specificity. Limit of quantification (LOQ) was also determined. Five batches of the proposed product were analyzed for PCDD and

#### Batch ID:

PCDF content.

- 1. 201409008
- 2. 201409009
- 3. 201409010
- 4. 201409011
- 5. 201409012

#### 5. Results:

The analysis for PCDDs and PCDFs indicates that no impurities were detected above the concentration of 0.1 ppb (parts per billion). No impurities were determined above the LOQ (limit of quantification). See the confidential appendix for tabulated data.

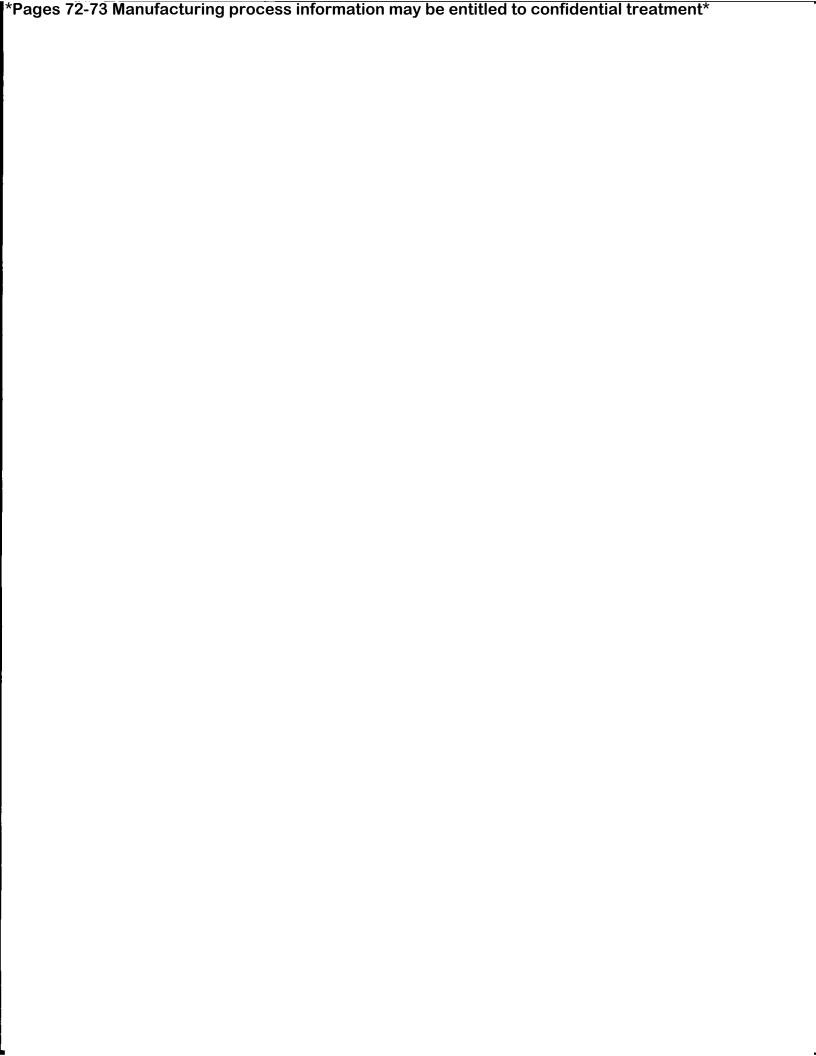
6.	In an e-ma	il corresponder	nce dated Marcl	n 19, 2015	, the registrant	states that	<u> </u>	

#### **CONCLUSIONS:**

The CITAB has reviewed the product chemistry data submitted for the proposed manufacturing use product and has concluded that:

- 1. The basic formula CSF for the proposed manufacturing use product, AgSaver Dicamba Technical dated 09 Feb 2015 is acceptable.
- 2. This submission satisfies the data requirements as specified in 40 CFR 158.320, 158.340 and 158.345 with respect to product identity and composition, the discussion of the formation of impurities and preliminary analysis. The impurity profile has been adequately detailed.
- 3. This submission satisfies the data requirement as specified in 40 CFR 158.310 with respect to physical and chemical properties for density (830.7300).

\*Manufacturing process information may be entitled to confidential treatment\*





### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

### OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DP BARCODE No.: 417765; FILE SYMBOL No.: 85806-U; PRODUCT NAME: AgSaver Dicamba Technical; DECISION No.: 485797; PC Code(s): 029801; ACTION CODE: R334; FOOD Use: Yes

DATE:

August 21, 2014

SUBJECT:

Product Chemistry Review of AgSaver Dicamba Technical"

FROM:

Shyam Mathur, Ph. D

Product Chemistry Team Leader

Technical Review Branch/RD (7505P)

TO:

Grant Rowland / Kathryn Montague, RM 23

Herbicide Branch / RD (7505P)

REGISTRANT: AGSAVER II, LLC

USE: Herbicide

FOOD USE: Yes [X] No []

MRID Numbers: 492733-01 to 492733-03

### **Table of Contents**

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DP BARCODE No.: 417765; FILE SYMBOL No.: 85806-U; PRODUCT NAME: AgSaver Dicamba Technical; DECISION No.: 485797; PC Code(s): 029801; ACTION CODE: R334; FOOD Use: Yes

#### INTRODUCTION:

Sullivan Worcester on behalf of the registrant AgSaver II, LLC has submitted an application for the registration of the new technical product AgSaver Dicamba technical. The registrant has submitted a CSF for basic formulation (dated November 13, 2013) and the supporting product chemistry data (group A & group B) with MRID Nos. 492733-01 to 492733-03. The Dicamba technical is produced by TRB has been asked to evaluate and determine the acceptability of the proposed basic CSF (dated 11-13-2013) and the supporting product chemistry data.

#### SUMMARY OF FINDINGS:

- 1. The findings for Group A guideline data were as follows:
  - 830.1550 (product identity & composition): The registrant has submitted a CSF for basic formulation (dated 11-13-2013). The product chemistry data corresponding to this guideline submitted on the CSF doe not satisfy the data requirements of 40CFR§158.320. The nominal concentration 98.9% for AI concurs with the product label claim nominal concentration of 98.9%. No analysis for polychlorinated dioxins & furans was done [MRID 492733-01].
- 830.1600 (description of materials used to produce the product): The product chemistry data submitted corresponding to this guideline satisfy the data requirements of 40CFR§ 158.325. The registrant has submitted the MSDS's for all the starting materials used to produce the dicamba technical [MRID No. 492733-01].
- 830.1620 (description of production process): The product chemistry data submitted corresponding to this guideline satisfy the data requirements for 40CFR§158.330. The crude dicamba technical was produced in leading to dicamba with 98% purity. The details of the production process have been provided by the registrant [MRID No. 492733-01].
- 830.1670 (discussion on the formation of impurities): The product chemistry data submitted corresponding to this guideline does not satisfy the data requirements for 40CFR§158.340. The registrant has listed only one impurity (in the proposed basic CSF 11-13-2013) which was identified and detected at the concentration of >0.1% in addition to water. Two other minor impurities were also detected at the concentrations of <0.1%. The registrant has provided the mechanisms of the formation of potential impurities in dicamba technical. No analysis was done to determine the presence of the impurities of tox concern like polychlorinated dioxins & dibenzofurans. These impurities must be identified and reported with their levels in the product [MRID No. 492733-01].
- 830.1700 (preliminary analysis): The product chemistry data submitted corresponding to this guideline to support the claims on the CSF does not satisfy the data requirements of 40CFR§158.345. The five lots of the test substance were analyzed to verify the concentration of Dicamba technical. The study was conducted at Nutrichem Laboratory Ltd., Beijing, China. The Al content and impurities were determined by HPLC-UV method. For the AI, the UV detector was operating at 230 nm and for impurities at 210 nm. The quantitation was done by using external standard technique. The analytical methods have been validated for linearity, accuracy and precision. No analysis was conducted for the impurities of tox concern like polychlorinated dioxin and dibenzofurans [MRID No. 492733 -02].

\*Product ingredient source information may be entitled to confidential treatment\*

<sup>\*</sup>Manufacturing process information may be entitled to confidential treatment\*

DP BARCODE No.: 417765; FILE SYMBOL No.: 85806-U; PRODUCT NAME: AgSaver Dicamba Technical; DECISION No.: 485797; PC Code(s): 029801; ACTION CODE: R334; FOOD Use: Yes

- 830.1750 (certified limits): The product chemistry data submitted corresponding to this guideline satisfy the requirements of 40CFR§158.350. The nominal concentrations for the active ingredient and the impurities are based on the five batch analysis [MRID No. 492733-01].
- 830.1800 (enforcement analytical method): The product chemistry data submitted corresponding to this guideline satisfy the requirements of 40CFR§158.355. The content of the active ingredient was determined by using HPLC-UV (280 nm) external standard technique. The analytical method was validated for precision, accuracy and linearity. [MRID No. 492733-01].
- 2. The 830 series group B guideline data (physical-chemical properties) submitted satisfy the data requirements of 40CFR§158.310(e), except for the guideline 830.7300 (density). The registrant has conducted accelerated studies for the guidelines 8307317 (storage stability) and 830.6320 (corrosion characteristics) and the test substance was found to be stable and no corrosive characteristics was observed for 2 weeks at 54 deg C. The Density value provided in the data does not concur with that given in the proposed basic CSF (4.85 g/cc vs 1.46 g/cc) [MRID No. 492733-03].

#### **CONCLUSIONS:**

The TRB has reviewed the product chemistry data submitted for proposed to support the proposed revised basic CSF and has concluded that:

- 1. The product chemistry data submitted for guideline 830 Series group A are partially acceptable. No analysis (830.1700) was conducted for impurities of tox concern like polychlorinated dioxins & dibenzo furans. There are ingredients in the manufacturing process which may be responsible for the formation of these kind of impurities under the reaction conditions of the process. The registrant is recommended to do analysis for polychlorinated dioxins & dibenzofurans. These impurities if detected (at any levels) must be listed on the CSF.
- 2. The proposed CSF for basic formulation (dated 11-13-2014) is not acceptable. The registrant must submit the revised basic CSF as per Item #1.
- 3. The product chemistry data submitted and cited for guideline 830 Series group B are acceptable. The registrant must clarify the correct value of density of the proposed product. The Density value provided in the data does not concur with that given in the proposed basic CSF (4.85 g/cc vs 1.46 g/cc).

\*Product ingredient source information may be entitled to confidential treatment\*

830.1550. Product identity & composition: (MRID No. 492733-01)

#### **Manufacturer Details**

COMMON NAME:

Dicamba (ISO)

STRUCTURAL FORMULA:

**EMPIRICAL FORMULA:** 

C<sub>8</sub>H<sub>6</sub>Cl<sub>2</sub>O<sub>3</sub>

M.W.:

221.0

CAS No.:

1918-00-9

PC Code:

29801

**CHEMICAL NAME:** 

3,6-dichloro-o-anisic acid

SYNONYMS:

Dicamba acid,

Benzoic acid, 3,6-dichloro-2-methoxy-

\*Product ingredient source information may be entitled to confidential treatment\*

\*Manufacturing process information may be entitled to confidential treatment\*

DP BARCODE No.: 417765; FILE SYMBOL No.: 85806-U; PRODUCT NAME: AgSaver Dicamba Technical; DECISION No.: 485797; PC Code(s): 029801; ACTION CODE: R334; FOOD Use: Yes

#### Group A Data

GLN	Requirement	MRID	Status	Details and /or Deficiency
830.1550	Product Identity and composition	49273301	N	Submitted basic CSF (dated 11-13-2013) with NC of 98.9% for the Al.
830.1600	Description of materials used to produce the product	a u	A	Submitted the MSDS's for all the starting materials used in the synthesis of Dicamba technical by
830.1620	Description of production process	u u	A	The Dicamba technical was produced in The The manufacturing process has been described in detail. The quality assurance procedures adopted in each step of the process have been included.
830.1670	Discussion of formation of impurities	49273301	N	Impurities discussed and identified. The discussions on the mechanisms of the formation of all impurities listed on the CSF have been provided. Only one impurity has been listed in the CSF. The registrant has not identified and not listed polychlorinated dioxins & dibenzofurans. No analysis was done.
830.1700	Preliminary analysis	49273302	N	The HPLC-UV method has been used for the determination, identification and quantitation of the active ingredient dicamba and the associated impurities. The details of the methods have been submitted along with the validation which included linearity, precision and accuracy, Lod & LOQ. No analysis was done for the toxic impurities like polychlorinated dioxins & dibenzofurans.
830.1750	Certified limits	49273301	A	The proposed limits for the AI and the impurities are based on five batch analysis.
830.1800	Enforcement analytical method	49273301	A	The HPLC/UV (280 nm) method was used for the determination of the Al contents. The external standard quatification technique was used. The method was validated for precision, linearity and accuracy.

U = Up-grade (additional information required);

830 Series Subgroup B (Physical-Chemical properties)

	0 Series Subgroup B (Physical-Chemical properties)  Table 2: Physical and Chemical Properties of : AgSaver Dicamba TGAI/MUP						
GLN	Requirement	MRID	Status	Result or Deficiency			
830.6302	Color	49273303	Α	Off-white			
830.6303	Physical state		Α	Solid (fine powder)			
830.6304	Odor	u u	Α	Mild			
830.6313	Stability to normal and elevated temperatures, metals, and metal ions		A	Stable at room temperature and also for 2 weeks at 54°C. Since the TS will not come in contact with metal & metal ions, this test is not required.			
830.6314	Oxidation/reduction: chemical incompatibility	49273303	A	The TS was found to be compatible with water, 5% ammonium phosphate, Fe powder, %5 Potassium permanganate and Aromatic 200 fluid.			
830.6315	Flammability		NA				
830.6316	Explodability		NA				
830.6317	Accelerated Storage stability	49273303		Stable for 2 weeks at 54°C.			
830.6319	Miscibility		NA	·			
830.6320	Corrosion characteristics	49273303	A	No corrosion seen on the pouches made of polyethylene lined woven polymer fabric identical to the material used in commercial packaging (Super Sacks) when stored for 2 weeks at 54°C.			
. 830.7000	рН	49273303	Α .	1.99 (1% dispersion) at 25°C			
830.7050	UV/Visible absorption	49273303	Α	See Note 1 below			
830.7100	Viscosity		NA				
830.7200	Melting point	49273303	Α	114-116°C			
830.7220	Boiling point		NA				
830.7300	Density	49273303	U	Reported 4.86 g/cc; in the CSF it is 1.48 g/cc			
830.7370	Dissociation constants in water (DC)	43288001	cited				
830.7550	Partition coefficient	41966601	cited				
830.7840	Water solubility:	44520902	cited				
830.7950	Vapor pressure	445209021	cited				

A = Acceptable; N = unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress or need upgrade; U = Upgrade (additional information required)

Note1. 830.7050 (UV-VIS): (MRID No. 49273303)

Table 4. UV/Visible Absorption of Dicamba 98%

Conditions	Neutral Solution	Acidic Solution	Basic Solution
Concentration	2.3529 x 10 <sup>-5</sup> M	3.0553 x 10 <sup>-5</sup> M	5.0921 x 10 <sup>-5</sup> M
Peak Wavelengths	204.6 nm	201.7 nm	216.3 nm
Absorbance Maximum	0.7497 AU	1.0245 AU	0.6166 AU
Molar Absorptivity	32,000	34,000	12,000
Bandwidth	20 nm	20 nm	34 nm

CONFIDENTIAL APPENDIX





## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

### OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

DATE February 4 2014

#### **MEMORANDUM**

Subject:

EPA File Symbol/Reg. No.: 85806-U

Product Name: AgSaver Dicamba Technical

DP Barcode: D417732 Decision No.: 485797 Action Code: R334 PC Code: 029801

From:

John C. Redden, M.S.

Technical Review Branch (TRB)

Registration Division (7505P)

Through:

**OPP Similarity Clinic** 

To:

Grant Rowland, RM23

Herbicide Branch (HB)

Registration Division (7505P)

Applicant:

Agsaver II, LLC

203 East Ash Street Mcgehee, AR 71654

Active Ingredient

% by weight

 Dicamba (3,6-dichloro-o-anisic acid).
 98.9%

 Inert Ingredients.
 1.1%

 100.0%

#### **OPP Similarity Clinic**

EPA File Symbol.: 85806-U EPA Reg. No. Cited: 42750-57

Reference information for review of cited data: The applicant cited EPA Reg. No. 42750-57 (Albaugh Technical Dicamba Acid MUP) and the acute toxicity studies cited in the Dicamba Reregistration Eligibility Decision (EPA-HQ\_OPP-2005-0479; FRL-8078-6).

#### Summary/Findings:

#### Tox Profile:

These are the acute toxicity studies extracted from the Dicamba RED.

MRID's	Gldn#	Acceptable	Results	Tox. Cat.
		Y/N		
00078444	81-1	Y	$LD_{50} \ge 2740 \text{ mg/kg/day}$	III
00241584	81-2	Y	$LD_{50} \ge 2000$ mg/kg	III
00263861	81-3	Y	$LC_{50} \geq 5.3 \text{ mg/L}$	IV
00241584	81-4	Y	irritant	II
00237955	81-5	Y	irritant	II
00263861	81-6	Y	negative	N/A

However TRB is using the precautionary language from EPA Reg. No. 42750-57, which the applicant cited. In addition, TRB is uncertain of the purity of the acute studies cited in the RED.

#### **LABELING**:

KEEP OUT OF REACH OF CHILDREN

#### **DANGER**

#### IF IN EYES:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
- Call a poison control center or doctor for treatment adive.

#### IF SWALLOWED:

- Call poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by the poison control center or doctor.
- Do not give anything by mouth to an unconscious person.

#### IF ON SKIN OR CLOTHING:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

#### HAZARDS TO HUMANS AND DOMESTIC ANIMALS

**DANGER:** Corrosive. Causes irreversible eye damage. Harmful if swallowed. Do not get in eyes, on skin, or on clothing. Wear protective eyewear (goggles or face shield). Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before resuse.

Sullivan & Worcester LLP 1666 K Street, NW Washington, DC 20006 T 202 775 1200 F 202 293 2275 www.sandw.com

December 11, 2013

Via Courier

#### **CONTAINS CONFIDENTIAL BUSINESS INFORMATION**

Document Processing Desk (REGFEE) Office of Pesticide Programs U.S. Environmental Protection Agency One Potomac Yard Room S-4900 2777 S. Crystal Drive Arlington, VA 22202

ATTN: Kathryn Montague, Product Manager #23

Re: Application for Registration of AgSaver<sup>TM</sup> Dicamba Technical, EPA Reg. No. 85806¥()

Dear Ms. Montague:

On behalf of AGSAVER II, LLC, we are submitting an application for a me-too registration of AgSaver<sup>TM</sup> Dicamba Technical, EPA Reg. No. 85806-I.

We are submitting this application as a PRIA Action Code R334, New product; MUP with unregistered source of the active ingredient. We are using the selective method of data citation and cite-all option for selected data requirements. The product is being registered for Terrestrial Food Crop; Terrestrial Nonfood Crop, and Terrestrial Noncrop uses for which US EPA has accepted required data and/or citations of data in support of registration.

#### Please find attached:

- 1. Transmittal Document
- 2. Application Form (EPA Form 8570-1)
- 3. Confidential Statement of Formula, dated 11/15/2013 (EPA Form 8570-4)
- 4. Certification with Respect to Citation of Data, dated 12/9/2013 (Form 8570-34)
- 5. Data Matrix, dated 11/18/2013 (EPA Form 8570-35, Agency and Public Use)
- 6. 5 copies of proposed label, dated 11/26/2013
- 7. 3 copies each of the study reports
- 8. A copy of a letter from AgSaver II showing Sullivan & Worcester LLP as authorized agent.
- 9. A copy of the PRIA fee email receipt.

The Preliminary Analysis study (Guideline 830.1700, Volume 3 of this submission) has been previously submitted and reviewed by EPA/OPP. The MRIDs for these previously submitted

Page 2

December 11, 2013

studies are: 47634901, 48420502 and 49206102. To the best of my knowledge this study has been found to be acceptable.

We have sent Offer-to-Pay letters to all the entities listed at the bottom of the Data Matrix.

If you have any questions regarding this submission, please do not hesitate to contact me.

Best regards,

Robert G. Butz

Staff Scientist/ Authorized Agent

Rest S. But

Direct line: 202-775-1211

rbutz@sandw.com

Attachments

cc: Telisport W Putsavage, Sullivan & Worcester

Clarke Pugh, AgSaver II, LLC

#### TRANSMITTAL DOCUMENT

#### Submitter:

AgSaver II, LLC 203 East Ash Street McGehee, AR 71654

**EPA Company Number 85806** 

**Company Contact:** 

Robert G. Butz, Staff Scientist/Authorized Agent

Relat S. But

Sullivan & Worcester LLP 1666 K St. NW, Suite 700 Washington, DC 20006

Phone: 202-775-1211

Email Address: rbutz@sandw.com

#### Regulatory Action in Support of Which this Package is Submitted:

Application for "Me-too" Registration of AgSaver Dicamba Technical (85806-4) U

#### **Submission Date:**

12/1/2013

#### **List of Submitted Documents:**

orm (EPA Form 8570-1) tatement of Formula, dated 11/13/2013 70-4)	
tatement of Formula, dated 11/13/2013 70-4)	
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oposed label, dated 11/26/2013)	,
of 3 enclosed reports	
AgSaver II letter showing Sullivan & Pas authorized agent.	
fee payment email receipt	
	lated 11/15/2013 (EPA Form 8570-35, ublic Use) oposed label, dated 11/26/2013) of 3 enclosed reports AgSaver II letter showing Sullivan &

Volume 2	Butz, R. G. 2013. AgSaver Dciamba Technical: Description of Beginning Materials and Manufacturing Process, Discussion of Formation of Impurities and Certified Limits. OCSPP 830.1550, 830.1600, 830.1620 830.1670 and 830.1750. Report No. Dicamba -001. 132 pages.	49273301
Volume 3	Li, H. 2008. Preliminary Analysis and Enforcement Method of Dicamba TGAI. OCSPP 830.1700 and 830.1800. Nutrichem Laboratory Co. Ltd. Report No. NC-2007-024. 1/27/2008. 91 pages.	49273302
Volume 4	Miller, R.L. 2013. Physical and Chemical Characteristics of Dicamba 98%. OCSPP 830.6302, 830.6303, 830.6304, 830.6313, 830.6314, 830.6317, 830.6320 830.7000, 830.7200, & 830.7300. ARC, Inc. Report No. ARC-EX-1265-017-P-1. 10/30/2013. 72 pages.	49273303



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## Date: November 18, 2013 Applicant's/Registrant's Name and Address: AgSaver II, LLC 203 E. Ash Ave. McGehee, AR 71654 Ingredient: Dicamba EPA Reg No./ File Symbol 85806-% t/J Product: AgSaver Dicamba Technical

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
<del>-</del> 11	Product Properties				
830.1550	Product Identity and Composition	Volume 2	AgSaver II, LLC	OWN	
830.1600	Description of materials used to produce the product	Volume 2	AgSaver II, LLC	OWN .	<b>'</b>
830.1620	Description of production process	Volume 2	AgSaver II, LLC	OWN	
830.1670	Formation of Impurities	Volume 2	AgSaver II, LLC	OWN	
<b>§30.1700</b>	Preliminary Analysis	Volume 3	AgSaver II, LLC	OWN	
830.1750	Certification of Limits	Volume 2	AgSaver II, LLC	OWN	
830.1800	Analytical Method	Volume 3	AgSaver II, LLC	OWN	
830.6302	Color	Volume 4	AgSaver II, LLC	OWN	
830.6303	Physical Stare	Volume 4	AgSaver II, LLC	OWN	· · · · · · · · · · · · · · · · · · ·
830.6304	Odor	Volume 4	AgSaver II, LLC	OWN	
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	Volume 4	AgSaver II, LLC	OWN	

Signature	Name and Title	Date
11 50 7 1	Robert G. Butz,	11/18/2013
Relait S, South	Authorized Agent for AgSaver II, LLC	
	Sullivan & Worcester LLP	

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U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC 20460. Do not send the form to this address.							
DATA MATRIX							
Date:	EPA Reg No./ File Symbol	Page 2 of 14					
November 18, 2013	85806- <b>L</b> U	1					
Applicant's/Registrant's Name and Address:	Product:						
AgSaver II, LLC							
203 E. Ash Ave.	AgSaver Dicamba Technical						
McGehee, AR 71654							
Ingredient: Dicamba	•						

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6314	Oxidation/reduction: Chemical Incompatibility	Volume 4	AgSaver II, LLC	OWN	
830.6315	Flammability	N/A	AgSaver II, LLC	N/A	N/A per/830.1000
830.6316	Explodability	N/A	AgSaver II, LLC	N/A	N/A per 830.1000
830.6320	Corrosion Characteristics	Volume 4	AgSaver II, LLC	OWN	
830.6376	Storage Stability	Volume 4	AgSaver II, LLC	OWN	
830.7000	рН	Volume 4	AgSaver II, LLC	OWN	
830.7050	UV/Visible Absorption	Volume 4	AgSaver II, LLC	OWN	
830.7200	Melting Point	Volume 4	AgSaver II, LLC	OWN	
830.7300	Density	Volume 4	AgSaver II, LLC	OWN	
830.7370	Dissociation Constants in Water	43288001, 43140308, 44520902	SANDOZ AGRO INC, SANDOZ AGRO INC ALBAUGH INC	OLD OLD OLD	
830.7550	Partition coefficient, shake flask method	41966601 23106	SANDOZ AGRO INC VELSICOL CHEMICAL CORP	OLD OLD	

Signature	Name and Title	Date
	Robert G. Butz,	11/18/2013
Mari S, Suit	Authorized Agent for AgSaver II, LLC	
	Sullivan & Worcester LLP	

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## Date: November 18, 2013 Applicant's/Registrant's Name and Address: AgSaver II, LLC 203 E. Ash Ave. McGehee, AR 71654 Ingredient: Dicamba

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7570 V	Octanol/Water Partition	44520902	ALBAUGH INC	OLD	
830.7840 <sub>V</sub>	Solubility	23106, _44520902	VELSICOL CHEMICAL CORP ALBAUGH INC	OLD OLD	
830.7950 √	Vapor Pressure	23106	VELSICOL CHEMICAL CORP	OLD	
	Fate, Transport and Transformation				
835.1240	Leaching/Adsorption/Desorption	42774101, 43095301	Sandoz Agro, Inc. Sandoz Agro, Inc.	OLD OLD	
835.1410	Laboratory Volatilization	41966602	Sandoz Crop Prot. Corp.	OLD	
835.2120	Hydrolysis	40335501	Velsicol Chemical Corporation,	OLD	<del></del>
835.2240	Photodegradation - Water	42774103	Sandoz Agro, Inc	OLD	
835.2410	Photodegradation - Soil	42774103	Sandoz Agro, Inc	OLD	
835.4100 🗸 .	Aerobic Soil Metabolism	43245207	Sandoz Agro. Inc	OLD	····
835.4200	Anaerobic Soil Metabolism	43245208	Sandoz Agro. Inc	OLD	
835.4300	Aerobic Aquatic Metabolism	43758509	Sandoz Agro. Inc	OLD ,	

Signature	Name and Title	Date
11 40 7 1	Robert G. Butz,	11/18/2013
Mari S, Suit	Authorized Agent for AgSaver II, LLC	
	Sullivan & Worcester LLP	

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## Date: November 18, 2013 Applicant's/Registrant's Name and Address: AgSaver II, LLC 203 E. Ash Ave. McGehee, AR 71654 Ingredient: Dicamba EPA Reg No./ File Symbol 85806-\( \) Page 4 of 14 85806-\( \) 85806-\(

Guideline Reference Number		Guideline Study Name	MRID Number	Submitter	Status	Note
835.4400 V		Anaerobic Aquatic Metabolism	43245208	Sandoz Agro. Inc	OLD	
835.6100		Terrestrial Field Dissipation	42754101, 42754102, 44361526	Sandoz Agro, Inc. Sandoz Agro, Inc. UNKNOWN	OLD OLD OLD	
835.8100	J	Fate in Soil - Leaching & Adsorption/Desorption	48876002 47434312	MONSANTO U.S. EPA	(PL)	
,		Spray Drift				
840.1100	$\vee$	Spray Droplet Size Spectrum	Cite-all	Spray Drift Task Force	PAY	
840.1200	<b>√</b>	Spray Drift Field Deposition	Cite-all	Spray Drift Task Force	PAY	
		Ecological Effects				<u>-</u>
850.1010	~	Freshwater Invertebrate Toxicity	00052126	VELSICOL CHEMICAL CORP	OLD	
850.1010	N	Invertebrate Toxicity - TEP	40094602	U.S. FISH & WILDLIFE	(PL)	-
850.1025	γ	Estuarine/Merine Toxicity - Mollusk	40228401	U.S. EPA	OLD	
850.1035	V	Estuarine/Marine Toxicity - Shrimp	00034702	VELSICOL CHEMICAL CORP	OLD	

Signature	Name and Title	Date
014074	Robert G. Butz,	11/18/2013
Mari S, Sut	Authorized Agent for AgSaver II, LLC	
	Sullivan & Worcester LLP	

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# Date: November 18, 2013 Applicant's/Registrant's Name and Address: AgSaver II, LLC 203 E. Ash Ave. McGehee, AR 71654 Ingredient: Dicamba EPA Reg No./ File Symbol 85806-Y U Page 5 of 14 85806-Y U AgSaver Dicamba Technical

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.1075	Fish Toxicity Bluegill	00034703	VELSICOL CHEMICAL CORP	OLD	
850.1075	Fish Toxicity Bluegill — TEP	40098001	US Fish & Wildlife Service	PL	
850.1075	Freshwater Fish Toxicity Rainbow Trout	00041272	VELSICOL CHEMICAL CORP	OLD	
850.1075	Freshwater Fish Toxicity Rainbow Trout - TEP	00036915	VELSICOL CHEMICAL CORP	OLD	
850.1075	Estuarine/Marine Toxicity - Fish	00025390 45205107	VELSICOL CHEMICAL CORP U.S. EPA	OLD PL	-
850.2100	Avian Acute Oral Toxicity-Duck	42774106	SANDOZ AGRO INC	OLD OLD	
850.2100	Avian Acute Oral Toxicity-Quail	42774105	SANDOZ AGRO INC	OLD	
850.2300	Avian Reproduction - Quail	43814004	SANDOZ AGRO INC	OLD	
850.2300	Avian Reproduction — Duck	43814003	SANDOZ AGRO INC	OLD	. <u>.</u>
850.3020	Horey Bee Acute Contact	00036935	ENIMONT AMERICA, INC	OLD	_
850.4100	Seedling Sermination and Seedling Emergence, Tier I	42846301	SANDOZ AGRO INC	OLD	

Signature	Name and Title	Date
11 40 7 1	Robert G. Butz,	11/18/2013
Mari S. Suit	Authorized Agent for AgSaver II, LLC	
	Sullivan & Worcester LLP	

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## Date: November 18, 2013 Applicant's/Registrant's Name and Address: AgSaver II, LLC 203 E. Ash Ave. McGehee, AR 71654 Ingredient: Dicamba EPA Reg No./File Symbol 85806-LU Page 6 of 14 85806-LU AgSaver Dicamba Technical

Guideline Refer Number	ence	Guideline Study Name	MRID Number	Submitter	Status	Note
850.4150		Vegetative Vigor, Tier I	42846301	SANDOZ AGRO INC	OLD	
850.4200	( )	Effects on Non-Target Plants - Seed Germination & Vegetative Vigor	48718014	BASF CORPORATION	PAY	
850.4225	V	Seedling Germination and Seedling Emergence, Tier II	48001301	BASF CORPORATION	PAY	•
850.4250	V	Vegetative Vigor, Tier II	48001302	BASF CORPORATION	PAY	
850.4400	,	Aquatic Plant Toxicity testing using Lemna, sp.	45088212	U.S. EPA	PL.	
850.5400		Aquatic Plant Growth	42774107, 42774108, 42774109, 42774100, 42774110	SANDOZ AGRO INC SANDOZ AGRO INC SANDOZ AGRO INC SANDOZ AGRO INC SANDOZ AGRO INC	OLD OLD OLD OLD OLD	
		Residue Chemistry				
860.1300		Nature of Residue — Plants	40642801	SANDOZ AGRAO INC	OLD	
860.1300		Nature of Residue — Livestock	43461701	WELLMARK INTERNATIONAL	OLD	

Signature	Name and Title	Date
11 40 7 1	Robert G. Butz,	11/18/2013
Helant S. Suit	Authorized Agent for AgSaver II, LLC	
	Sullivan & Worcester LLP	,

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## Date: November 18, 2013 Applicant's/Registrant's Name and Address: AgSaver II, LLC 203 E. Ash Ave. McGehee, AR 71654 Ingredient: Dicamba EPA Reg No./ File Symbol 85806-4 U Page 7 of 14 Reg No./ File Symbol 85806-4 U Re

Guideline Reference	Guideline Study Name	MRID	Submitter	Status	Note
Number		Number			
860.1340	Residue Analytical Method — Plants	40233501,	SANDOZ AGRO INC	OLD	
		40547911,	SANDOZ AGRO INC	OLD	
		41187301,	SANDOZ AGRO INC	OLD	
		42675901,	SANDOZ AGRO INC	OLD	
		42883202,	SANDOZ AGRO INC	OLD	
		43245203,	SANDOZ AGRO INC	OLD	
	,	43245205,	SANDOZ AGRO INC	OLD	
		43245205,	SANDOZ AGRO INC	OLD	ŕ
		43245206,	SANDOZ AGRO INC	OLD	
l		43274501,	SANDOZ AGRO INC	OLD	
		43370701,	WELLMARK INTERNATIONAL	OLD	
1		43425803,	SANDOZ AGRO INC	OLD	
	,	, 43866601,	SANDOZ AGRO INC	OLD	
		<b>√</b> 43814101,	SANDOZ AGRO INC	OLD	
	•	44089302,	SANDOZ AGRO INC	OLD	
		44089303,	SANDOZ AGRO INC	OLD	
		44089304,	SANDOZ AGRO INC	OLD	
1	1	44089305,	SANDOZ AGRO INC	OLD	
		44891302,	BASF CORPORATION	PAY	

Signature	Name and Title	Date
1014074	Robert G. Butz,	11/18/2013
16 Let S, Suit	Authorized Agent for AgSaver II, LLC	
	Sullivan & Worcester LLP	

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## Date: November 18, 2013 Applicant's/Registrant's Name and Address: AgSaver II, LLC 203 E. Ash Ave. McGehee, AR 71654 Ingredient: Dicamba EPA Reg No./ File Symbol 85806-1 () Page 8 of 14 85806-1 () AgSaver Dicamba Technical

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		44891303,	BASF CORPORATION	PAY	
	1	45196801,	BASE CORPORATION	PAY	
	1	43814001	SANDOZ AGRO INC	OLD	
		48001303	BASF CORP	PAY	
860.1340	Residue Analytical Method - Livestock	Data gap		GAP	RED
860.1360	Multiresidue Methods	48001304	BASF CORP	PAY	
860.1380 · √	Storage Stability- sugarcane molasses	Data gap		GAP	RED
860.1380 <sub>N</sub>	Storage Stability- animal commodities	Data gap		GAP	RED
ه 60.1480	MOR - Cattle, Goats, Horses and Sheep Meat	00079742	VELSICOL CHEMICAL CORP	OLD	
860.1480	MOR - Cattle, Goats, Horses and Sheep Meat Byproducts	00079742	VELSICOL CHEMICAL CORP	OLD	
860.1480	MOR - Cattle, Goats, Horses and Sheep Fat	00079742	VELSICOL CHEMICAL CORP	OLD	
860.1480	MOR - Mill:	00116671	VELSICOL CHEMICAL COR	OLD	
860.1500	MOR - Corn, Grain	44089303	SANDOZ AGRO INC	OLD	

_ <del></del>	·			
Signature			Name and Title	Date
11 40	7 1	ļ F	Robert G. Butz,	11/18/2013
What S,	Sut		Authorized Agent for AgSaver II, LLC	
	- 1	] 8	Sullivan & Worcester LLP	

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## Date: November 18, 2013 Applicant's/Registrant's Name and Address: AgSaver II, LLC 203 E. Ash Ave. DATA MATRIX EPA Reg No./ File Symbol 85806-X, (/) Page 9 of 14 85806-X, (/) Product: AgSaver Dicamba Technical

McGehee, AR 71654 Ingredient: Dicamba

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1500	MOR - Corn, Stover	44089303	SANDOZ AGRO INC	OLD	
860.1500	MOR - Corn, Sweet	48001305	BASE CORPORATION	PAY,	
860.1500	Corn, Forage	44089303	SANDOZ AGRO INC	OLD	
860.1500	MOR - Soybean, forage	40001901 41387001	SANDOZ AGRO INC SANDOZ AGRO INC	OLD OLD	
860.1500	MOR - Soybean, hay	40001901 41387001	SANDOZ AGRO INC SANDOZ AGRO INC	OLD OLD	
860.1500	MOR - Sugarcane	00030701 44089302	VELSICOL CHEMICAL CORP SANDOZ AGRO INC	OLD OLD	
ತ60.1500	MOR - Sorghum, Grain	43245203	SANDOZ AGRO INC	OLD	
860.1500	MOR -Sorghum, Stover	44089306	SANDOZ AGRO INC	OLD	
860.1500	MOR - Sorghum, Forage	43245203	SANDOZ AGRO INC	OLD	
860.1500	MCR - Stalk, Stem, and Leaf Petiole Vegetables	48499801	INTERREGIONAL RESEARCH PROJECT NO. 4 (IR-4)	PL	
860.1500	MOR - Wheat, Grain	44089305	SANDOZ AGRO INC	OLD	

Signature	Name and Title	Date
West S, Suit	Robert G. Butz, Authorized Agent for AgSaver II, LLC Sullivan & Worcester LLP	11/18/2013

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## Date: November 18, 2013 Applicant's/Registrant's Name and Address: AgSaver II, LLC 203 E. Ash Ave. McGehee, AR 71654 Ingredient: Dicamba EPA Reg No./File Symbol 85806-1, i) Page 10 of 14 85806-1, i) Page 10 of 14 85806-1, i) Page 10 of 14 85806-1, ii 8580

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1500	MOR - Wheat, Forage	43274501	SANDOZ AGRO INC	OLD	
860.1500	MOR - Wheat, Straw	44089305	SANDOZ AGRO INC	OLD	-
860.1520	Magnitude of Residue in Processed Food/Feed; Wheat	40663801, 42675901	SANDOZ AGRO INC SANDOZ AGRO INC	OLD OLD	
860.1560	Reasonable Grounds in Support of Petition - Exposure or Risk to Non-Target Organisms	48457909	U.S. EPA	PL	
860.1850	Confined Accumulation in Rotational Crops	41972001, 43698601	SANDOZ WELLMARK INTERNATIONAL	OLD OLD	
<u> </u>	Health Effects				
870.1100	Acute Oral Toxicity	00078444	VELSICOL CHEMICAL CORP	OLD	RED
870.1200	Acute Dermal Toxicity	00241584	UNKNOWN	OLD	RED
870.1300	Acute Inhalation Toxicity	00263861	UNKNOWN	OLD	RED
870.2400	Acute Eye In tation	00241584	UNKNOWN	OLD	RED
870.2500	Acute Dermal Irritation	00237955	UNKNOWN	OLD	RED

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Signature		• "- '-	Name and Title	Date
121 50	>	<i>i</i>	Robert G. Butz,	11/18/2013
Ilder S,	South	<del></del>	Authorized Agent for AgSaver II, LLC	
			Sullivan & Worcester LLP	

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## Date: November 18, 2013 Applicant's/Registrant's Name and Address: AgSaver II, LLC 203 E. Ash Ave. McGehee, AR 71654 Ingredient: Dicamba EPA Reg No./ File Symbol 85806¾ ¿/ Product: AgSaver Dicamba Technical

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.2600	Dermal Sensitization	00263861	UNKNOWN	OLD	RED
870.3100	Subchronic Oral Toxicity: 90- Day Study Rodent	44623101	BASE CORPORATION	OLD	
870.3150	Subchronic Oral Toxicity: 90- Day Study Non-rodent	44623101	BASF CORPORATION	OLD	
870.3200	21-Day Dermal - Rabbit/Rat	40547901, 45814501	SANDOZ AGRO INC BASF CORPORATION	OLD OLD	
870.3550	Developmental Toxicity - Mice	46074401	U.S. EPA	PL	
870.3700	Developmental Toxicity - Rat	00084024	Velsicol Chemical Corp.	OLD	
870.3700	Developmental Toxicity - Rabbit	42429401	SANDOZ AGRO INC	OLD	
870.3800	2-Generation Reproduction - Rat	43137101	SANDOZ AGRO INC	OLD	
870.4100	Chronic Feeding Toxicity - Rat	42774104	SANDOZ AGRO INC	OLD	
870.4100	Chronic Feeding Toxicity Study - Rat	00145150	E. I. DUPONT DE NEMOURS	OLD	
870.4100	Chronic Feeding Toxicity Study - Non-rodent	40321102, 43245210	SANDOZ AGRO INC SANDOZ AGRO INC	OLD OLD	

Signature	Name and Title	Date
11 40 -7 1-	Robert G. Butz,	11/18/2013
Mart S. Sut	Authorized Agent for AgSaver II, LLC	
	Sullivan & Worcester LLP	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version. {W0258448; 1}



WASHINGTON, D.C. 20460

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## Date: November 18, 2013 Applicant's/Registrant's Name and Address: AgSaver II, LLC 203 E. Ash Ave. McGehee, AR 71654 Ingredient: Dicamba EPA Reg No./ File Symbol 85806-k. () Product: AgSaver Dicamba Technical

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.4200	Carcinogenicity Mice	40872401	SANDOZ AGRO INC	OLD	
870.4300	Combined Chronic Toxicity/Carcinogenicity: Rats	00145150	E. I. DUPONT DE NEMOURS	OLD	
870.5100	Bacterial Reverse Gene Mutation	40321101	SANDOZ AGRO INC	OLD	
870.5375	Cytogenetics	40321101, 00143001	SANDOZ AGRO INC VELSICOL CHEMICAL CORP	OLD OLD	
870.5550	Unscheduled DNA Synthesis in Mammalian Cells in Culture	00143001	VELSICOL CHEMICAL CORP	OLD	
870.7485	General Metabolism	44609801	BASF CORPORATION	OLD	
870.7800	Immunotoxicity	48081601	BASF CORP	PAY	
	Occupational and Residential Exposure				
875.1000	Background for Application Exposure Monitoring	Cite-All	AHETF	PAY	
875.1100	Oer.nal Exposure -Outdoor	Cite-All	AHETF	PAY	
875.1200	Derma Exposure - Indoor	Cite-All	ARTF, AHETF	PAY	
875.1300	Inhalation Exposure -Outdoor	Cite-All	ARTF. AHETF	PAY	

Signature
Robert S. But

Name and Title
Robert G. Butz,
Authorized Agent for AgSaver II, LLC
Sullivan & Worcester LLP

Date 11/18/2013

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WASHINGTON, D.C. 20460

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	DATA MATRIX	•
Date:	EPA Reg No./ File Symbol	Page 13 of 14
November 18, 2013	85806-₩ U	
Applicant's/Registrant's Name and Address:	Product:	•
AgSaver II, LLC		
203 E. Ash Ave.	AgSaver Dicamba Technical	
McGehee, AR 71654		
Ingredient: Dicamba		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
875.1400	Inhalation Exposure -Indoor	47464517	U.S. EPA	PL	
875.2100	Foliar Dislodgeable Residue Dissipation	Cite-All	ARTF	PAY	
875.2200	Soil Residue Dissipation	44959001 47299308	SYNGENTA CROP PROTECTION, LLC U.S. EPA	PAY PL	RED <sup>1</sup>
875.2400	Dermal Exposure - Postapplication	Cite-All	ARTF	PAY	
875.2500	Inhalation Exposure - Postapplication	Cite-All	ARTF	PAY	
Special	Exposure or Risk to Non-Target organisms	Cite-All	Generic Endangered Species Task Force	PAY	

Signature Relat 2, But	Name and Title Robert G. Butz, Authorized Agent for AgSaver II, LLC	Date 11/18/2013
L L	Sullivan & Worcester LLP	

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WASHINGTON, D.C. 20460

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DATA MATRIX			
Date:	EPA Reg No./ File Symbol P	age 14 of 14	
November 18, 2013	85806-¥_ ()		
Applicant's/Registrant's Name and Address:	Product:		
AgSaver II, LLC			
203 E. Ash Ave.	AgSaver Dicamba Technical		
McGehee, AR 71654			
Ingredient: Dicamba			

#### **End Notes**

1. This study is classified as an 875.2200 study in the Dicamba RED, but in NPIRS appears as an 875.2100 study. The study title also indicates it is probably an 875.2100 study.

#### AgSaver II, LLC will make offers-to-pay to the following entities on the Data Submitters List of September 25, 2013:

- AGRICULTURAL HANDLER EXPOSURE TASK FORCE
- 2. AGRICULTURAL REENTRY TASK FORCE
- 3. BASE CORPORATION
- 4. GENERIC ENDANGERED SPECIES TASK FORCE
- 5. SPRAY DRIFT TASK FORCE
- 6. SYNGENTA CROP PROTECTION, LLC

Signature	Name and Title	Date
11 40 7 1	Robert G. Butz,	11/18/2013
Mari S. Suit	Authorized Agent for AgSaver II, LLC	
	Sullivan & Worcester LLP	

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## Certification with Respect to Label Integrity

version: 9/11/02

I certify that the information (including, but not limited to, text, tables, and graphics) contained in the electronic file identified below by file name and submitted with this certification is the same information as that on the paper copies of these documents included with this submission.

PROPOSED LABEL		
EPA Registration #	Date Submitted to EPA	Electronic file name
85806-I		085806-xxxxx.20140919.AgSaverDicambaTechn icalW0271189.pdf

I certify that the statements that I have made on this form are true, accurate, and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.

grisum egelus)	9/19/2104
Signature	Date

Janine M. Gydus Name (typed)

Scientist/Authorized Agent for AgSaver II, LLC Title

{W0271154; 1}

#### AgSaver II, LL C PO Box 111 McGehee, AR 71654

September 19, 2013

#### Via Email

Document Processing Desk (COADR)
Attention: Kathleen O'Malley
U.S. Environmental Protection Agency
Office of Pesticide Programs
Room S4900, One Potomac Yard
2777 Crystal Drive
Arlington, VA 22202

Email: Omalley.kathleen@epa.gov

Re: Change in Authorized Company Representative for AgSaver II, LLC, EPA

Company Number 85806

To Whom It May Concern:

This letter authorizes the following firm to act as our authorized agent in all pesticide registration matters. This authorization shall take effect immediately.

Sullivan & Worcester LLP 1666 K Street, NW, Suite 700 Washington, DC 20006 202-775-1200

If you have any questions, please call me at (870) 222-5395. Thank you.

Sincerely,

Clarke Pugh

203 East Ash Street McGehee, AR 71654

Clarke PS1

cc: Janine Gydus, Sullivan & Worcester LLP

{W0260851; 1}

Please read instructions on rever	se before completing form		For				060, Approval expires 5-31-98
United States				Registration		on	OPP Identifier Number
<b>EPA</b> Environmental Protection Agency		$\dashv$ ,	Amendme	ent			
		X	Other				
		ton, DC 20460	D (I I O (I	<u> </u>	<del></del>		
Application for Pesticide – Section I							
1. Company/Product Number EPA Reg. No. 85806-U	ſ		EPA Product Ma     Kathryn Montague	anage	r	3. Propo	osed Classification
4. Company/Product (Name)			PM#			X No	one Restricted
AgSaver™ Dicamba Techni	cal		23			<u> </u>	<u> </u>
<ol><li>Name and Address of App AGSAVER II, LLC</li></ol>	olicant (Include ZIP Code)						FRA Section 3(c)(3) cosition and labeling
P. O. Box 111			to:	, 5	ur or 10011110		oodion and taboling
MCGEHEE, AR 71654			EPA Reg No.				
Check if this is a new ac	ddress		Product Name				
		Se	ction – II				
Amendment – Explain b	elow			label	s in respon	se to Age	ncy letter dated
				<del></del>			
Resubmission in respon	nse to Agency letter dated		"Me Too" Ap	plicat	ion		
Notification – Explain be	elow		X Other – Exp	lain be	elow		
Explanation: Use additional	page(s) if necessary. (Fo mal Product Chemistry stu	r Section I and	Section II.)	0/23/	2014		
For PRIA decision code	D-485797		Agency in a letter dated	3/23/	2014.		
Point of Contact: Robert	Butz rbutz@sandw.com 2					· · · · · · · · · · · · · · · · · · ·	
		Se	ction III				
Material This Product Will     Child-Resistant Packaging	be Packaged in: Unit Packaging		Water Soluble Packagin			2 Tvn	e of Container
Yes Yes	Yes		Yes Yes	9			etal
X No	X No		X No				lastic
<b>                                     </b>						₁ <b>; ;</b> ;	lass
*Certification must	If "Yes" Unit Packaging wgt.	No. per container	if "Yes" Package wgt		. per ntainer		aper ther (Specify <u>) woven bag</u>
be submitted	Onit Fackaging wgt.	Container	r ackage wgt	(0)	illaine:		ned w/ polyethylene bag
3. Location of Net Contents I	nformation		etail Container	<u> </u>	5. Loc		bel directions
X Label	Container	800 kg				On Label	
6. Manner in Which Label is	Affived to Product	Lithogr		X	Other Lab		accompanying product
G. Wallier III Wallicht Laber 197	Allixed to Floddot	X Paper o			Other Lat	rei iii poac	<del></del>
Stenciled							
	<del></del> _		ction IV				
Contact Person (Complete	items directly below for it		ndividual to be contacted	, if ne			
Name		Title   Staff So	ientist			ephone No -775-1211	o. (Include Area Code)
Robert G. Butz		Sullivar	n & Worcester LLP				
		Authori	zed Agent for AgSaver	II, LL	.с		
		rtification			1	E	i. Date Application
I certify that the statements I h			•		•		Received
I acknowledge that any knowing both under applicable law	ngiy taise or misleading sta	tement may be p	ounisnable by line or impr	rsonm	ient or		•• •
2. Signature		3. Title					(Stamped)
Reat S	0 7 _		ientist, Sullivan & Wor				• •••••
16 ment	0, 5	Authori	zed Agent for AgSaver	II, LL	.C		••••
4. Typed Name		5. Date	ry 9, 2015				• • • • • • • • • • • • • • • • • • • •
Robert G. Butz		repruai	y ə, 201ə				••••
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{W0274158; 1}



### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Janine Gydus Agsaver II, LLC P.O. Box 111 Mcgehee, AR 71654

SEP 23 2014

Subject: - Application for 85806-U

Product Name: AgSaver<sup>TM</sup> Dicamba Technical EPA Application Dated: December 11<sup>th</sup>, 2014

Decision Number: 485797

Dear Ms. Gydus,

The application referred to above has been determined, pursuant to 40 CFR 152.105, not to be sufficient for further processing. The items specified below must be addressed before processing of the application can be completed. If such deficiencies cannot be corrected within 75 days from the date of this letter, you must notify the Agency within those 75 days of the date you expect to complete the application. If, after 75 days, you do not respond, or you subsequently fail to complete the application within the scheduled times of completion, the Agency will terminate any action on the application, and will treat the application as if it has been withdrawn by you. As you see fit, you may also withdraw the registration application.

- No analysis (830.1700) was conducted for impurities of tox concern such as polychlorinated dioxins and dibenzo furans. There are ingredients in the manufacturing process which may be responsible for the formation of these kinds of impurities under the reaction conditions of the process. In order to correct this deficiency, please conduct an analysis at the currently accepted "State of the Art" level of detection (LOD) and report the top 17 impurities of tox concern on your CSF. Please note that you must also include non-detects on your CSF as well.

The current PRIA date for this action is 12/1/2014. Please contact the Agency regarding renegotiation of the due date, as it is not possible to have the above-mentioned deficiencies submitted and reviewed prior to the current due date. The renegotiated PRIA due date for this action will be extended by at least 90 days after we receive your resubmission. If you have any questions regarding these comments or the PRIA due date, please feel free to contact Grant Rowland at 703-347-0254 or via email at rowland.grant@epa.gov

Singerely,

Kathryn V Montague

Product Manager 23

Herbicide Branch

Registration Division (7505P)

Recommendation of Division Directors  Negotiated Due Dates							
Decision #:485797	Registration #:8580	6-U F	Petition #:				
			,				
See page 2 for additional registration entries	1	1					
Chemical Name: Dicamba							
Fee Category: R334		PRIA D	ecision Time Frame: 11 months				
Submitted by: Grant	Rowland	Branch:	Branch: OCSPP/OPP/RD Date: 11/25/2014				
Company: AgSaver							
Original PRIA Due Date: 12/01/20	)15	Proposed New PRIA	<b>Due Date:</b> 03/31/2015				
Previous Negotiated Due Dates:							
Is the "Fix" in-house? Yes	No ✓ n/a	If not, date "Fix	" expected:				
Negotiated Due Date Reason:  Additional Data Required    V   Product Chemistry							
Data Deficiencies Envir	ronmental Ecolog						
<del>   -</del> -	an Health Ecolog	·					
	Interim Consideration Agency Initiated Registrant Initiated						
CSF							
Summary of Deficiency Type(s):       □ Not Submitted (N)       □ Deficiencies (D)         Product Chemistry:       ✓ Acute Tox:       □ Efficacy:       □ Labeling:       □ Ecological Data:       □ Other (describe):							
Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates):  The registrant agreed to the terms listed out in a 75 day letter sent on Sept 23, 2015. Once the registrant was able to schedule the necessary analysis needed with an approved lab, they contacted the EPA with a confirmation of completion date and agreed to a new PRIA date of 90 days out from when the data will be submitted to the Agency.							
"75 Day" Letter sent? Ves, Date sent09/23/2015 No and reason for none? Add comments on page 2							
Rationale for Proposed Due Date: 90 days from the date that the new data is submitted							
Registrant notified that this is the last negotiation? Yes Vot Applicable							
Approve: Disapprove:							
If disapproved, action to be taken:							
OD or DOD Signature:			Date:				

Decision #: 485797	Registration #:85806-U	Petition #:				
T ()(1 19 1 1 1 19						
Issue(s) (describe in detail):  No analysis (830.1700) was conducted for impurities of tox concern such as polychlorinated dioxins and dibenzo furans. There are						
ingredients in the manufacturing process of Dicamba which may be responsible for the formation of these kinds of impurities under the reaction conditions of the process. In order to correct this deficiency, one must conduct an analysis at the currently accepted "State of the Art" level of detection (LOD) and report the top 17 impurities of tox concern on their CSF.						
•						
		•				
Comment(s):						
		•				
•						
	•					

### **Audit Trail for**

## Recommendation of Division Directors Negotiated Due Dates

PDF Name: PRIAv5.pdf

Form Number: PRIA

Document Identifier: PRIA-14329105909-GR

SUBMITTED on 11/25/2014 at 11:22:57 AM by CN=Grant Rowland/OU=DC/O=USEPA/C=US

#### Rowland, Grant

From:

Butz, Ph.D., Robert G. <rbutz@sandw.com> Thursday, November 20, 2014 5:45 PM

Sent: To:

Rowland, Grant

Subject:

AgSaver Dicamba Technical

Grant.

By this email AgSaver II LLC agrees to a renegotiated PRIA due date of March 31, 2015 for the PRIA Decision No. 485797.

Please email or call me if you need anything else.

--Bob Butz

Robert G. Butz, Ph.D. Staff Scientist/ Authorized Agent **Sullivan and Worcester LLP** 1666 K Street, NW Washington, DC 20006

Phone: 202 775 1211

Email: rbutz@sandw.com

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#### Rowland, Grant

From:

Gydus, Janine M. <jgydus@sandw.com>

Sent:

Friday, September 19, 2014 10:11 AM

To:

Rowland, Grant

Cc:

Putsavage, Telisport W.; Butz, Ph.D., Robert G.

Subject:

RE: Minor errors in draft labeling for AgSaver Dicamba Technical, OPP Decision No.

D-485797

Attachments:

Cert for Elect Label 085806-xxxxx.20140919.AgSaverDicambTechW0271189

(W0271190).PDF; 085806-xxxxx.20140919.AqSaverDicambaTechnicalrevW0271189

(W0271189).PDF

Grant,

Thank you for the opportunity to make minor changes to the draft label. Please find attached revised labeling for AgSaver Dicamba Technical, OPP Decision No. D-485797. I have also included Certification with Respect to Label Integrity.

- 1. I added brackets in Container Handling to show that certain text will only be used for applicable container type/size.
- 2. I changed "Do not reuse or refill this bag" to "Do not reuse or refill this container" because a bag or drum may be used.

[Non-refillable Exterior Container] [Exterior Bag:] [OR] [Exterior Drum:] [Nonrefillable container. Do not reuse or refill this bag. Completely empty removable liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into equipment. Then dispose of empty container in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by other procedures.]

Thank you,

Janine M. Gydus
Staff Scientist
Sullivan & Worcester LLP
1666 K Street, NW • Washington, DC 20006
T 202 775 1235
F 202 293 2275
jgydus@sandw.com

From: Rowland, Grant [mailto:Rowland.Grant@epa.gov]

Sent: Friday, September 19, 2014 9:27 AM

To: Gydus, Janine M.

www.sandw.com

Cc: Putsavage, Telisport W.; Butz, Ph.D., Robert G.

Subject: RE: Minor errors in draft labeling for AgSaver Dicamba Technical, OPP Decision No. D-485797

Hello Janine,

Yes, sending me a new label is not a problem at all. Please send away.

On a different note regarding this product, I recently received the Product chemistry review back and there was in fact an issue with your data. I am in the midst of Drafting you an official letter, but I thought I would give you a heads up considering time may be of a factor. The EPA technical review branch noted the following:

- No analysis (830.1700) was conducted for impurities of tox concern such as polychlorinated dioxins and dibenzo furans. There are ingredients in the manufacturing process which may be responsible for the formation of these kinds of impurities under the reaction conditions of the process. In order to correct this deficiency, please conduct an analysis at the currently accepted "State of the Art" level of detection (LOD) and report the top 17 impurities of tox concern on your CSF. Please note that you must also include non-detects on your CSF as well

Again, I will be sending you out an official letter early next week, but hopefully this gives you some additional time to start preparing. Please feel free to contact me with any questions you may have.

-Grant

Grant Rowland
Herbicide Branch
Registration Division
Office of Pesticide Programs
703-347-0254

From: Gydus, Janine M. [mailto:jgydus@sandw.com]

Sent: Friday, September 19, 2014 9:06 AM

To: Rowland, Grant

Cc: Putsavage, Telisport W.; Butz, Ph.D., Robert G.

Subject: FW: Minor errors in draft labeling for AgSaver Dicamba Technical, OPP Decision No. D-485797

Good morning, Grant.

Kay Montague sent me an email earlier this week (see below) that I may email a revised draft label for AgSaver Dicamba Technical, OPP Decision No. D-485797. Would you please confirm that you will permit this? The changes are very minor. Thank you.

Janine M. Gydus
Staff Scientist
Sullivan & Worcester LLP
1666 K Street, NW • Washington, DC 20006
T 202 775 1235
F 202 293 2275
jgydus@sandw.com
www.sandw.com

From: Montague, Kathryn V. [mailto:Montague.Kathryn@epa.gov]

Sent: Monday, September 15, 2014 9:58 AM

To: Gydus, Janine M.; Rowland, Grant

Cc: Putsavage, Telisport W.; Butz, Ph.D., Robert G.

Subject: RE: Minor errors in draft labeling for AgSaver Dicamba Technical, OPP Decision No. D-485797

Hi, Janine,

I'm forwarding this email to the reviewer, Grant Rowland. I think you should still be able to send us a revised label – Grant, can you confirm? Via email is fine, no need to go through the front end.

Best Regards,

Kay

From: Gydus, Janine M. [mailto:jgydus@sandw.com]

Sent: Friday, September 12, 2014 2:15 PM

To: Montague, Kathryn V.

Cc: Putsavage, Telisport W.; Butz, Ph.D., Robert G.

Subject: Minor errors in draft labeling for AgSaver Dicamba Technical, OPP Decision No. D-485797

Kathryn,

We submitted an application for registration for AgSaver Dicamba Technical on December 11, 2013 and EPA assigned the application an OPP Decision No. of 485797. I found a couple of typos in the container handling directions of the draft labeling.

First, there should be brackets around directions for the disposable liner to indicate that it is optional and the directions only will be only label when a liner is used.

And, secondly, "Do not reuse or refill this bag" for the statement below should instead state "Do not reuse or refill this container" because a bag or drum may be used.

[Non-refillable Exterior Container] [Exterior Bag:] [OR] [Exterior Drum:] [Nonrefillable container. Do not reuse or refill this bag. Completely empty removable liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into equipment. Then dispose of empty container in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by other procedures.]

Is it too late to submit a revised label prior to registration? If it is not too late, may I send revised labeling to you by email or do I need to submit via Document Processing?

Thank you,
Janine M. Gydus
Staff Scientist
Sullivan & Worcester LLP
1666 K Street, NW • Washington, DC 20006
T 202 775 1235
F 202 293 2275
igydus@sandw.com
www.sandw.com

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## Certification with Respect to Label Integrity

/ersion: 9/11/02

I certify that the information (including, but not limited to, text, tables, and graphics) contained in the electronic file identified below by file name and submitted with this certification is the same information as that on the paper copies of these documents included with this submission.

PROPOSED LABEL								
EPA Registration #	Date Submitted to EPA	Electronic file name						
85806-I		085806-xxxxx.20140919.AgSaverDicambaTechn icalW0271189.pdf						

I certify that the statements that I have made on this form are true, accurate, and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.

Buiremagus)	9/19/2104
Signature	Date

Janine M. Gydus Name (typed)

Scientist/Authorized Agent for AgSaver II, LLC Title

Hue

#### TRANSMITTAL DOCUMENT

#### Submitter:

AgSaver II, LLC 203 East Ash Street McGehee, AR 71654

EPA Company Number 85806

#### **Company Contact:**

Robert G. Butz, Staff Scientist/Authorized Agent

Ret S. But

Sullivan & Worcester LLP 1666 K St. NW, Suite 700 Washington, DC 20006

Phone: 202-775-1211

Email Address: rbutz@sandw.com

#### Regulatory Action in Support of Which this Package is Submitted:

Submission of Additional Product chemistry study for "Me-too" Registration of AgSaver Dicamba Technical (85806-U), Decision # D-485797

#### **Submission Date:**

2/9/2015

#### **List of Submitted Documents:**

		MRID
Volume 1	Administrative Materials: 1. Application Form (EPA Form 8570-1) 2. Confidential Statement of Formula, dated 2/09/2015 (EPA Form 8570-4)	
Volume 2	Sun, Gang. 2015. Polychlorinated Dibenzodioxins and Polychlorinated Dibenzofurans Analysis of Dicamba TGAI. OPPTS 830.1700, 830.1800. Southwest Research Institute. Project # 01.20881.01.001. GLP-SP-243. 2/6/2015. 59 pages	49565101



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M STREET, S.W. WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.							
Certification with Respect to Citation of Data							
Applicant's/Registrant's Name, Address, and Telephone Number AGSAVER II, LLC 203 EAST ASH STREET MCGEHEE AR 71654	EPA Registration Number/File Symbol 85806-1、 U						
Active Ingredient(s) and/or representative test compound(s) Dicamba, CAS Reg. No. 1918-00-9		Date November 18, 2013					
General Use Pattern(s) (list all those claimed for this product using 40 C Terrestrial Food Crop; Terrestrial Nonfood Crop, Terrestrial Noncre EPA has accepted required data and/or citations of data in supportuses for experimental purposes in compliance with US EPA.							
NOTE: If your product is a 100% repackaging of another purchased EF to submit this form. You must submit the Formulators Exemption States							
I am responding to a Data-Call-In Notice, and have included w should be used for this purpose).	rith this form a list of c	companies sent offers of compensation (the Data Matrix form					
SECTION I: METHOD OF DA	TA SUPPORT (Chec	k one method only)					
I am using the cite-all method of support, and have included w this form a list of companies sent offers of compensation (the I Matrix form should be used for this purpose)	Data X ui a	am using the selective method of support (or cite-all option or inder the selective method), and have included with this form completed list of data requirements (the Data Matrix form ust be used).					
SECTION II: G	ENERAL OFFER TO	PAY					
[Required if using the cite-all method, or when using the cite-all option u	under the selective mo	ethod to satisfy one or more data requirements]					
I hereby offer and agree to pay compensation, to other person	s, with regard to the a	approval of this application, to the extent required by FIFRA					
SECTION	III: CERTIFICATION						
I certify that this application for registration, this form for reregistration or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section 1, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.							
I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data subrities of that I have obtained the written permission of the original data submitted to cite that study.							
I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I enrette original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application or original data submitter; (c) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.							
I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence efficient delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.							
I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment of both under applicable law.							
Signature	Date	Typed or Printed Name and Title					
Olanki Rh	12/9/13	Clarke Pugh, Member, AgSaver II, ŁLC					

EPA Form 8570-34 (9-97) Electronic and Paper versions available. Submit only Paper version.

#### Butz, Ph.D., Robert G.

From:

Clarke Pugh <clarkepugh@yahoo.com>

Sent:

Monday, December 09, 2013 3:56 PM

To:

Butz, Ph.D., Robert G.

Subject:

Fw: Pay.gov Payment Confirmation: PRIA Service Fees

---- Forwarded Message -----

From: "paygovadmin@mail.doc.twai.gov" <paygovadmin@mail.doc.twai.gov>

To: "clarkepugh@yahoo.com" <clarkepugh@yahoo.com>

Sent: Monday, December 9, 2013 2:48 PM

Subject: Pay.gov Payment Confirmation: PRIA Service Fees

Your payment has been submitted to Pay.gov and the details are below. If you have any questions or you wish to cancel this payment, please contact Pay.gov Customer Service by phone at (800) 624-1373 or by email at pay.gov.clev@clev.frb.org.

Application Name: PRIA Service Fees Pay.gov Tracking ID: 25DFK2UU Agency Tracking ID: 74540780511

Transaction Type: Sale

Transaction Date: Dec 9, 2013 3:48:42 PM

Account Holder Name: Clarke Pugh Transaction Amount: \$18,893.00 Billing Address: PO Box 121

City: McGehee State/Province: AR Zip/Postal Code: 71654

Country: USA

Card Type: AmericanExpress
Card Number: \*\*\*\*\*\*\*\*7008

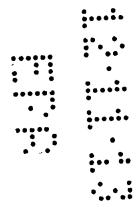
**Decision Number:** 

Registration Number: 85806-I Company Name: AgSaver II, LLC

Company Number: 85806

Action Code: R334

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.



# PRIA 3 – 21 Day Content Screen Review Worksheet (EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: Fee Paid: Yes Experts In-Processing Signature: \_\_ Date / Division management contacted on issues

	ion management contacted on issues Noi esi					
EPA I	Reg. Number: 85806-4 EPA Receipt Date: 12	111/	13			
Items for Review					No	N/A*
1	Application Form (EPA Form 8570-1) signed & complete including package type					
2	Confidential Statement of Formula all boxes completed, form s dated (EPA Form 8570-4)	igned, a	nd	X		
2	a) All inerts, including fragrances, approved for the proposed uses (see Footnote A)	yes	no		· .	
3	Certification with Respect to Citation of Data (EPA Form 8570 completed and signed (N/A if 100% repack)	)-34)		X		
	Certificate and data matrix consistent			Y		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)					
	If applicable, is there a letter of Authorization for exclusive use or	ıly.				
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and					Х
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)					
5	a) Selective Method (Fee category experts use)	yes *	no			
	b) Cite-All (Fee category experts use)					
,	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of <u>Label</u> ( <u>Electronic labels on CD</u> are encouraged and guidance is available)					
7	Is the data package consistent with PR Notice 86-5			X		
8	Notice of Filing included with petitions					X

9	If applicable for conventional applications, reduced risk rationale		X
	Required Data and/or data waivers. See Footnote C.		
	a) List study (or studies) not included with application		
10	·		
10			
		·	

Comments: Studies passed 11-3 review. Pass 492733.

Technical and Impurities only, no iners to seview.

12/26/13 - An e-mail was sent to the registrant,

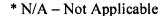
regarding the coverletter, application,

cert. form and data matrix, which had

the Reg. as 85806 - I. It should be 85806 - U.

and said I4 was obtaine to cross oux the Land para u.

\* See e-mail \*



#### Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are strongly encouraged to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency even if a product is currently registered by consulting the inert Web site and if the inert is not approved nor has an application pending with the Agency, to obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at <a href="inertsbranch@epa.gov">inertsbranch@epa.gov</a> and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the <a href="Chief of Microbial Pesticides Branch">Chief of Microbial Pesticides Branch</a>.

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.



During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

#### Unapproved Inerts Identified on CSFs

#### All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

- 1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
- 2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or
- 3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;
- 4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

#### Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

- Correct the application by, for instance, correcting the inert's identity or CAS
  number, providing documentation that the inert has been approved, or
  removing the unapproved inert from the CSF or replacing it with one that is
  approved for the application's uses; or
- 2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

#### **PIP Applications**

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

- 1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
- 2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.
- 3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

- B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.
- C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

#### Jackson, Tracy

From:

Butz, Ph.D., Robert G. [rbutz@sandw.com]

Sent:

Monday, December 30, 2013 9:38 AM

To:

Jackson, Tracy

Subject:

RE: Application Deficiencies (85806-U)

Tracy, OK to cross out and correct. Thanks.

--Bob Butz

Robert G. Butz, Ph.D. Staff Scientist Sullivan and Worcester LLP 1666 K Street, NW Washington, DC 20006

Phone: 202 775 1211

Email:

rbutz@sandw.com

----Original Message----

From: Jackson, Tracy [mailto:jackson.tracy@epa.gov]

Sent: Friday, December 27, 2013 9:34 AM

To: Butz, Ph.D., Robert G.

Subject: RE: Application Deficiencies (85806-U)

Hello Mr. Butz,

Should I cross out the I on all of the forms and put a U, or would you prefer to resend the forms with corrections?

Thank You Tracy Jackson

----Original Message----

From: Butz, Ph.D., Robert G. [mailto:rbutz@sandw.com]

Sent: Friday, December 27, 2013 9:29 AM

To: Jackson, Tracy

Subject: RE: Application Deficiencies (85806-U)

Tracy,

The -U is correct.

Robert Butz

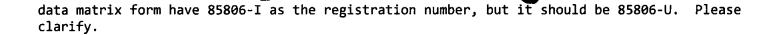
From: Jackson, Tracy [jackson.tracy@epa.gov] Sent: Thursday, December 26, 2013 8:40 AM

To: Butz, Ph.D., Robert G.

Subject: Application Deficiencies (85806-U)

Dear Mr. Butz,

I am contacting you regarding your submission in support of AgSaver Dicamba Technical (85806-U). The cover letter, application form, certification with respect to citation form and



Thank You

Tracy Jackson
EPA Contractor
703-308-7227
2777 S. Crystal Drive
Arlington, VA 22202

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Communications from our firm may contain or incorporate federal tax advice. Under US Internal Revenue Service (IRS) standards, we are required to inform you that only formal, written tax opinions meeting IRS requirements may be relied upon by taxpayers for the purpose of avoiding tax-related penalties. Accordingly, this communication is not intended or written to be used, and it cannot be used, for the purpose of avoiding tax-related penalties under the Internal Revenue Code. Please contact a member of our law firm's Tax Department if you require a formal, written tax opinion that satisfies applicable IRS requirements, or if you have any other questions regarding federal tax advice.

#### Jackson, Tracy

From:

Jackson, Tracy

Sent:

Thursday, December 26, 2013 8:40 AM

To:

'rbutz@sandw.com'

Subject:

Application Deficiencies (85806-U)

Dear Mr. Butz,

I am contacting you regarding your submission in support of **AgSaver Dicamba Technical (85806-U)**. The cover letter, application form, certification with respect to citation form and data matrix form have 85806-I as the registration number, but it should be 85806-U. Please clarify.

Thank You

Tracy Jackson EPA Contractor 703-308-7227 2777 S. Crystal Drive Arlington, VA 22202



### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

December 13, 2013

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

OPP Decision Number: D-485797

EPA File Symbol or Registration Number: 85806-U

Product Name: DICAMBA TECHNICAL

EPA Receipt Date: 11-Dec-2013 EPA Company Number: 85806

Company Name: AGSAVER II, LLC

ROBERT G. BUTZ SULLIVAN & WORCESTER LLP AGSAVER II, LLC 1666 K STREET, NW WASHINGTON, DC 20006

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

#### Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R334

NEW PRODUCT; MUP OR END USE PRODUCT WITH UNREGISTERED SOURCE OF THE ACTIVE INGREDIENT; REQUIRES SCIENCE DATA REVIEW; NEW PHYSICAL FORM; SELECTIVE DATA CITATION;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

Front End Processing Staff

Information Technology & Resources Management Division

## Fee for Service

{9448461~

This package includes the following	for Division				
<ul><li>New Registration</li><li>Amendment</li></ul>	○ AD ○ BPPD ● RD				
□ Studies? □ Fee Waiver? □ volpay % Reduction:	Risk Mgr. 23				
Receipt No. S-	944846				
EPA File Symbol/Reg. No.	85806-U				
Pin-Punch Date:	12/11/2013				
☐ This item is NOT subject t	o FFS action.				
Action Code:	Parent/Child Decisions:				
Requested: R34  Granted: R334  Amount Due: \$ 18 893					
☐ Inert Cleared for Intended Use	Uncleared Inert in Product				

Reviewer:\_

Remarks:

Date: 12-13-13

# **21-Day Screen Completed by Contractor**

21-Day Expires on \_/-/-/4

Jacket # 85806 - U MRID# 492733

Content Screen: Recommend to Pass/Fail

11-3 Review: Pass/Fail/NA

Overall Status: Recommend to Pass/Fail

Transfer This Jacket to:

STEPHEN SettAIBLE

Please read instructions on reverse before completing form			Form A			0, Approval expires 5-31-98			
Unite	d States		X	Registrati	on	OPP Identifier Number			
<b>EPA</b> Environmental F	dency		Amendme	ent					
	gency		Other						
	on, DC 20460	lecticide Cost	<u> </u>	1					
Application for Pesticide – Section I  1. Company/Product Number  2. EPA Product Manager  3. Proposed Classification									
1. Company/Product Number EPA File Symbol: 85806-F ( )		Kathryn Montague	Mana	ger	3. Proposed Classification				
4. Company/Product (Name)		PM#		,	X Nor	ne Restricted			
AgSaver™ Dicamba Technical  5. Name and Address of Applicant (Include ZIP Code)		23		In accordan	L L	DA Coetion 2/a\/2\			
AGSAVER II, LLC		Expedited Review. In accordance with FIFRA Section 3(c)(3)     (b)(i), my product is similar or identical in composition and labeling							
P. O. Box 111		to:							
MCGEHEE, AR 71654  Check if this is a new address		EPA Reg No. Product Name		<u>:750-57</u> _BAUGH TEC	HNICAL D	ICAMBA ACID			
	Sect	tion – II							
Amendment – Explain below			ted lat	oels in respon	se to Agend	cy letter dated			
Resubmission in response to Agency letter dated		X "Me Too"	Applic	cation					
Notification – Explain below		Other – E	xplain	below					
		L!							
Explanation: Use additional page(s) if necessary. (For registered for Terrestrial Food Crop; Terrestrial Nonfood citations of data in support of registration; and uses for experiment of Contact: Robert Butz rbutz@sandw.com	Crop, and Terro	estrial Noncrop uses	for wi	hich US EPA I	nas accepte	ed required data and/or			
Tollit of collabor Nobelt But Thursday Strict		tion III							
Material This Product Will be Packaged in:			•						
Child-Resistant Packaging Unit Packaging Yes Yes	\	Vater Soluble Packag ── Yes	jing		2. Type	of Container			
	-					stic			
X No		X No			│				
*Certification must If "Yes" Unit Packaging wgt.		"Yes" ackage wgt		No. per container	Pa <sub>l</sub> Oth	per ner (Specify)			
3. Location of Net Contents Information	4. Size(s) Reta	ail Container		<u>5. L</u> oc	ation of lab	el directions			
X Label Container				'	On Label				
6. Manner in Which Label is Affixed to Product	Lithograp	.h		Other	on Label ac	companying product			
o. Manner in William Laber is Allixed to Floddat	Paper glu					_			
	Stenciled								
		tion IV							
Contact Person (Complete items directly below for identified Name	Intification of inc	lividual to be contact	ed, if			s application.) (Include Area Code)			
Name	Staff Scie	entist			-775-1211	(IIIOlane Alea Code)			
Robert G. Butz  Sullivan & Worcester LLP Authorized Agent for AgSaver, LLC						• • •			
	tification				6.	Date Application			
I certify that the statements I have made on this form and a I acknowledge that any knowingly false or misleading state						Received			
both under applicable law					••	6 d@4mmn c.d\			
2. Signature	3. Title Staff Scie	entist, Sullivan & W	orcee	ter LLP	***	(Stamped)			
That &, Sof	ed Agent for AgSav			•••••	•				
4. Typed Name	5. Date	44 2042				•			
Robert G. Butz  EPA Form 8570-1 (Rev. 8-94) Previous editions are obsole		o <b>r 11, 2013</b> Wi	nite – I	EPA File Copy	(Original)	Yellow — Applicant Copy			

